Australian Government

Department of Health and Aged Care

# Schedule of Pharmaceutical Benefits

General Pharmaceutical Schedule - Volume 1

**Effective 1 September 2023**

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

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

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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 2023 and are included, where applicable, in prices published in the Schedule —

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $8.37 |
| | Dangerous drug fee | $5.18 |
| | Extemporaneously-prepared | $10.41 |
| | Allowable additional patient charge* | $3.29 |
| Additional Fees (for safety net prices): | Ready-prepared | $1.40 |
| | Extemporaneously-prepared | $1.80 |
| Patient Co-payments: | General | $30.00 |
| | Concessional | $7.30 |
| Safety Net Thresholds: | General | $1563.50 |
| | Concessional | $262.80 |
| Safety Net Card Issue Fee: | | $11.42 |

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

# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2023. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

## Prescriber Bag

### Additions

***Addition – Item***

13625D **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

***Addition – Equivalence Indicator***

3467L *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

***Addition – Note***

3467L **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

### Alterations

***Alteration – Manufacturer Code***

| | | *From* | *To* |
|---|---|---|---|
| 3455W | *Largactil* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules | SW | IX |

## General Pharmaceutical Benefits

### Additions

***Addition – Item***

13363H **ADAPALENE + BENZOYL PEROXIDE**, adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g *(Epiduo)*

13499L **ALENDRONATE**, alendronate 70 mg tablet, 4 *(APO-Alendronate, Alendronate Sandoz, Fonat)*

13358C **ALLOPURINOL**, allopurinol 100 mg tablet, 200 *(Allopurinol APOTEX, Allopurinol Sandoz, Allosig, NOUMED ALLOPURINOL, Progout 100, Zyloprim)*

13575L **ALLOPURINOL**, allopurinol 300 mg tablet, 60 *(Allopurinol APOTEX, Allopurinol Sandoz, Allosig, NOUMED ALLOPURINOL, Progout 300, Zyloprim)*

13410T **AMILORIDE + HYDROCHLOROTHIAZIDE**, amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50 *(Moduretic)*

13615N **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g *(Alfamino)*

13627F **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g *(Alfamino)*

13532F **AMLODIPINE**, amlodipine 5 mg tablet, 30 *(APO-Amlodipine, Amlo 5, Amlodipine APOTEX, Amlodipine Amneal, Amlodipine GH, Amlodipine Sandoz, BTC Amlodipine, Blooms Amlodipine, Blooms the Chemist Amlodipine, NOUMED AMLODIPINE, Nordip, Norvapine, Norvasc, Pharmacor Amlodipine)*

13562T **AMLODIPINE**, amlodipine 10 mg tablet, 30 *(APO-Amlodipine, Amlo 10, Amlodipine APOTEX, Amlodipine Amneal, Amlodipine GH, Amlodipine Sandoz, BTC Amlodipine, Blooms Amlodipine, Blooms the Chemist Amlodipine, NOUMED AMLODIPINE, Nordip, Norvapine, Norvasc, Pharmacor Amlodipine)*

13596N **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30 *(Cadivast 5/10)*

13567C **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30 *(Cadivast 5/20)*

13415C **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 40 mg tablet, 30 *(Cadivast 5/40, Caduet 5/40)*

13597P **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 80 mg tablet, 30 *(Cadivast 5/80, Caduet 5/80)*

13479K **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 10 mg tablet, 30 *(Cadivast 10/10, Caduet 10/10)*

13384K **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 20 mg tablet, 30 *(Cadivast 10/20, Caduet 10/20)*

13536K **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 40 mg tablet, 30 *(Cadivast 10/40, Caduet 10/40)*

13421J **AMLODIPINE + VALSARTAN**, amlodipine 5 mg + valsartan 80 mg tablet, 28 *(Exforge 5/80, Valsartan/Amlodipine Novartis 80/5)*

13516J **AMLODIPINE + VALSARTAN**, amlodipine 5 mg + valsartan 160 mg tablet, 28 *(Exforge 5/160, Valsartan/Amlodipine Novartis 160/5)*

13604B **AMLODIPINE + VALSARTAN**, amlodipine 5 mg + valsartan 320 mg tablet, 28 *(Exforge 5/320, Valsartan/Amlodipine Novartis 320/5)*

13454D **AMLODIPINE + VALSARTAN**, amlodipine 10 mg + valsartan 160 mg tablet, 28 *(Exforge 10/160, Valsartan/Amlodipine Novartis 160/10)*

13389Q **AMLODIPINE + VALSARTAN**, amlodipine 10 mg + valsartan 320 mg tablet, 28 *(Exforge 10/320, Valsartan/Amlodipine Novartis 320/10)*

13448T **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**, amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(Exforge HCT 5/160/12.5, Valsartan/Amlodipine/HCT Novartis 160/5/12.5)*

13603Y **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**, amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 *(Exforge HCT 5/160/25, Valsartan/Amlodipine/HCT Novartis 160/5/25)*

13390R **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**, amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 *(Exforge HCT 10/160/25, Valsartan/Amlodipine/HCT Novartis 160/10/25)*

13514G **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**, amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(Exforge HCT 10/160/12.5, Valsartan/Amlodipine/HCT Novartis 160/10/12.5)*

13573J **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**, amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 *(Exforge HCT 10/320/25, Valsartan/Amlodipine/HCT Novartis 320/10/25)*

13464P **APIXABAN**, apixaban 2.5 mg tablet, 60 *(Eliquis)*

13525W **APIXABAN**, apixaban 5 mg tablet, 60 *(Eliquis)*

13600T **ATENOLOL**, atenolol 50 mg/10 mL oral liquid, 300 mL *(Atenolol-AFT)*

13540P **ATENOLOL**, atenolol 50 mg tablet, 30 *(APO-Atenolol, APX-Atenolol, Atenolol Amneal, Atenolol GH, Atenolol Sandoz, Noten, Tenormin, Tensig)*

13495G **ATORVASTATIN**, atorvastatin 10 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 10, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

13529C **ATORVASTATIN**, atorvastatin 20 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 20, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

13468W **ATORVASTATIN**, atorvastatin 40 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 40, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

13374X **ATORVASTATIN**, atorvastatin 80 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 80, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

13623B **AZACITIDINE**, azacitidine 200 mg tablet, 7 *(Onureg)*

13619T **AZACITIDINE**, azacitidine 300 mg tablet, 7 *(Onureg)*

13624C **AZACITIDINE**, azacitidine 300 mg tablet, 7 *(Onureg)*

13522Q **BACLOFEN**, baclofen 10 mg tablet, 100 *(APO-Baclofen, Clofen 10, Lioresal 10, Stelax 10)*

13359D **BACLOFEN**, baclofen 25 mg tablet, 100 *(APO-Baclofen, Clofen 25, Lioresal 25, Stelax 25)*

13484Q **BALSALAZIDE**, balsalazide sodium 750 mg capsule, 280 *(Colazide)*

13419G **BISOPROLOL**, bisoprolol fumarate 2.5 mg tablet, 28 *(APO-Bisoprolol, Bicard 2.5, Bicor, Bisoprolol Dr.Reddy's, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 2.5, Cipla Bisoprolol, NOUMED BISOPROLOL)*

13443M **BISOPROLOL**, bisoprolol fumarate 5 mg tablet, 28 *(APO-Bisoprolol, Bicard 5, Bicor, Bisoprolol Dr.Reddy's, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 5, Cipla Bisoprolol, NOUMED BISOPROLOL)*

13444N **BISOPROLOL**, bisoprolol fumarate 10 mg tablet, 28 *(APO-Bisoprolol, Bicard 10, Bicor, Bisoprolol Dr.Reddy's, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 10, Cipla Bisoprolol, NOUMED BISOPROLOL)*

13520N **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g *(Enstilar)*

13577N **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g *(Calcipotriol/Betamethasone Sandoz 50/500, Daivobet)*

13457G **CALCITRIOL**, calcitriol 0.25 microgram capsule, 100 *(APO-Calcitriol, CALITROL, Calciprox, Calcitriol AN, Kosteo, Rocaltrol, Sical)*

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

13547B **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 240 *(Calci-Tab 600)*

13592J **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30 *(APO-Candesartan, Adesan, Atacand, BTC Candesartan, Blooms the Chemist Candesartan, CANDESAN, Candesartan Sandoz, NOUMED CANDESARTAN)*

13436E **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30 *(APO-Candesartan, Adesan, Atacand, BTC Candesartan, Blooms the Chemist Candesartan, CANDESAN, Candesartan Sandoz, NOUMED CANDESARTAN)*

13565Y **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30 *(APO-Candesartan, Adesan, Atacand, BTC Candesartan, Blooms the Chemist Candesartan, CANDESAN, Candesartan Sandoz, NOUMED CANDESARTAN)*

13438G **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30 *(APO-Candesartan, Adesan, Atacand, BTC Candesartan, Blooms the Chemist Candesartan, CANDESAN, Candesartan Sandoz, NOUMED CANDESARTAN)*

13391T **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Candesartan HCTZ 16/12.5, Adesan HCT 16/12.5, Atacand Plus 16/12.5, Blooms the Chemist Candesartan HCTZ 16/12.5, CANDESAN COMBI 16/12.5, Candesartan/HCT Sandoz, NOUMED CANDESARTAN/HCT)*

13452B **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Candesartan HCTZ 32/12.5, Adesan HCT 32/12.5, Atacand Plus 32/12.5, Blooms the Chemist Candesartan HCTZ 32/12.5, CANDESAN COMBI 32/12.5, Candesartan/HCT Sandoz, NOUMED CANDESARTAN/HCT)*

13392W **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30 *(APO-Candesartan HCTZ 32/25, Adesan HCT 32/25, Atacand Plus 32/25, Blooms the Chemist Candesartan HCTZ 32/25, CANDESAN COMBI 32/25, Candesartan/HCT Sandoz, NOUMED CANDESARTAN/HCT)*

13417E **CARVEDILOL**, carvedilol 6.25 mg tablet, 60 *(APO-Carvedilol, Carvedilol Sandoz, Carvidol, Dicarz, Dilatrend 6.25, Vedilol 6.25, Volirop 6.25)*

13418F **CARVEDILOL**, carvedilol 12.5 mg tablet, 60 *(APO-Carvedilol, Carvedilol Sandoz, Carvidol, Dicarz, Dilatrend 12.5, Vedilol 12.5, Volirop 12.5)*

13387N **CARVEDILOL**, carvedilol 25 mg tablet, 60 *(APO-Carvedilol, Carvedilol Sandoz, Carvidol, Dicarz, Dilatrend 25, Vedilol 25, Volirop 25)*

13500M **CHLORTALIDONE**, chlortalidone 25 mg tablet, 50 *(Hygroton 25)*

13578P **CLONIDINE**, clonidine hydrochloride 100 microgram tablet, 100 *(APO-Clonidine, Catapres 100, Clonidine Lupin)*

13548C **CLONIDINE**, clonidine hydrochloride 150 microgram tablet, 100 *(Catapres)*

13365K **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(BTC Clopidogrel, Clopidogrel GH, Clovix 75, Plidogrel)*

13399F **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(Clopidogrel Lupin, Clopidogrel Sandoz Pharma, Clopidogrel Winthrop, Iscover, Piax, Plavicor 75)*

13427Q **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30 *(APX-Clopidogrel/Aspirin 75/100, CLOPIDOGREL/ASPIRIN AN 75/100, Clopidogrel Winthrop plus aspirin, DuoCover, DuoPlidogrel, Piax Plus Aspirin)*

13523R **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 60 *(Pradaxa)*

13489Y **DABIGATRAN**, dabigatran etexilate 150 mg capsule, 60 *(Pradaxa)*

13369P **ENALAPRIL**, enalapril maleate 5 mg tablet, 30 *(APO-Enalapril, Acetec, Enalapril Sandoz, Enalapril generichealth, Malean)*

13465Q **ENALAPRIL**, enalapril maleate 10 mg tablet, 30 *(APO-Enalapril, Acetec, Enalapril Sandoz, Enalapril generichealth, Malean, Renitec)*

13401H **ENALAPRIL**, enalapril maleate 20 mg tablet, 30 *(APO-Enalapril, Acetec, Enalapril Sandoz, Enalapril generichealth, Malean, Renitec 20)*

13439H **ENALAPRIL + HYDROCHLOROTHIAZIDE**, enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30 *(Enalapril/HCT Sandoz, Renitec Plus 20/6)*

13590G **EPLERENONE**, eplerenone 25 mg tablet, 30 *(APO-Eplerenone, ESPLER, Inpler, Inspra)*

13379E **EPLERENONE**, eplerenone 50 mg tablet, 30 *(APO-Eplerenone, ESPLER, Inpler, Inspra)*

13440J **EZETIMIBE**, ezetimibe 10 mg tablet, 30 *(APO-Ezetimibe, BTC Ezetimibe, Blooms The Chemist Ezetimibe, EZEMICHOL, Ezetimibe GH, Ezetimibe Sandoz, Ezetrol, Pharmacor Ezetimibe 10, Zient 10mg)*

13480L **EZETIMIBE (&) ROSUVASTATIN**, ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60 *(Ezalo Composite Pack 10mg+20mg, Pharmacor Ezetimibe Rosuvastatin Composite Pack, Rosuzet Composite Pack)*

13537L **EZETIMIBE (&) ROSUVASTATIN**, ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60 *(Ezalo Composite Pack 10mg+40mg, Pharmacor Ezetimibe Rosuvastatin Composite Pack, Rosuzet Composite Pack)*

13569E **EZETIMIBE (&) ROSUVASTATIN**, ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60 *(Ezalo Composite Pack 10mg+10mg, Pharmacor Ezetimibe Rosuvastatin Composite Pack, Rosuzet Composite Pack)*

13629H **EZETIMIBE (&) ROSUVASTATIN**, ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60 *(Ezalo Composite Pack 10mg+5mg, Rosuzet Composite Pack)*

13539N **EZETIMIBE + ATORVASTATIN**, ezetimibe 10 mg + atorvastatin 10 mg tablet, 30 *(Atozet, Ezetast, Ezetimibe/Atorvastatin GH 10/10)*

13622Y **EZETIMIBE + ATORVASTATIN**, ezetimibe 10 mg + atorvastatin 20 mg tablet, 30 *(Atozet, Ezetast, Ezetimibe/Atorvastatin GH 10/20)*

13416D **EZETIMIBE + ATORVASTATIN**, ezetimibe 10 mg + atorvastatin 40 mg tablet, 30 *(Atozet, Ezetast, Ezetimibe/Atorvastatin GH 10/40)*

13538M **EZETIMIBE + ATORVASTATIN**, ezetimibe 10 mg + atorvastatin 80 mg tablet, 30 *(Atozet, Ezetast, Ezetimibe/Atorvastatin GH 10/80)*

13385L **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 10 mg tablet, 30 *(APO-Ezetimibe/Simvastatin 10/10, EZESIM 10/10, EZETIMIBE/SIMVASTATIN SANDOZ, EZETORIN, EZEVYT 10/10, EzSimva GH 10/10, Pharmacor Ezetimibe Simvastatin 10/10, Vytorin, Zeklen 10/10 mg)*

13442L **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 20 mg tablet, 30 *(APO-Ezetimibe/Simvastatin 10/20, EZESIM 10/20, EZETIMIBE/SIMVASTATIN SANDOZ, EZETORIN, EZEVYT 10/20, EzSimva GH 10/20, Pharmacor Ezetimibe Simvastatin 10/20, Vytorin, Zeklen 10/20 mg)*

13535J **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 40 mg tablet, 30 *(APO-Ezetimibe/Simvastatin 10/40, EZESIM 10/40, EZETIMIBE/SIMVASTATIN SANDOZ, EZETORIN, EZEVYT 10/40, EzSimva GH 10/40, Pharmacor Ezetimibe Simvastatin 10/40, Vytorin, Zeklen 10/40 mg)*

13595M **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 80 mg tablet, 30 *(APO-Ezetimibe/Simvastatin 10/80, EZESIM 10/80, EZETIMIBE/SIMVASTATIN SANDOZ, EZETORIN, EZEVYT 10/80, EzSimva GH 10/80, Pharmacor Ezetimibe Simvastatin 10/80, Vytorin, Zeklen 10/80 mg)*

13519M **FEBUXOSTAT**, febuxostat 80 mg tablet, 28 *(Adenuric)*

13377C **FELODIPINE**, felodipine 2.5 mg modified release tablet, 30 *(Felodur ER 2.5 mg, Fendex ER, Plendil ER)*

13561R **FELODIPINE**, felodipine 5 mg modified release tablet, 30 *(Felodil XR 5, Felodur ER 5 mg, Fendex ER, Plendil ER)*

13531E **FELODIPINE**, felodipine 10 mg modified release tablet, 30 *(Felodil XR 10, Felodur ER 10 mg, Fendex ER, Plendil ER)*

13469X **FENOFIBRATE**, fenofibrate 48 mg tablet, 60 *(APO-Fenofibrate, FENOFIBRATE RBX, Fenofibrate Cipla, Fenofibrate Viatris, Lipidil)*

13587D **FENOFIBRATE**, fenofibrate 145 mg tablet, 30 *(APO-Fenofibrate, Blooms the Chemist Fenofibrate, FENOFIBRATE RBX, Fenocol, Fenofibrate Cipla, Fenofibrate Sandoz, Fenofibrate Viatris, Lipidil)*

13558N **FLUVASTATIN**, fluvastatin 80 mg modified release tablet, 28 *(Lescol XL)*

13504R **FUROSEMIDE**, furosemide 10 mg/mL oral liquid, 30 mL *(Lasix)*

13473D **FUROSEMIDE**, furosemide 20 mg tablet, 100 *(APO-Frusemide, FUROSEMIDE AN, Frusemix-M)*

13501N **FUROSEMIDE**, furosemide 20 mg tablet, 50 *(Frusemix-M, Urex-M)*

13472C **FUROSEMIDE**, furosemide 40 mg tablet, 100 *(APO-Frusemide, FUROSEMIDE AN, Frusax, Frusemix, NOUMED FUROSEMIDE, Uremide, Urex)*

13474E **FUROSEMIDE**, furosemide 500 mg tablet, 50 *(Urex-Forte)*

13618R **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60 *(Ausgem, Lipigem)*

13612K **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

13614M **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

13490B **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30 *(Transiderm-Nitro 25)*

13580R **GLYCERYL TRINITRATE**, glyceryl trinitrate 10 mg/24 hours patch, 30 *(Transiderm-Nitro 50)*

13549D **GLYCERYL TRINITRATE**, glyceryl trinitrate 400 microgram/actuation spray, 200 actuations *(Nitrolingual Pumpspray)*

13409R **HYDROCHLOROTHIAZIDE**, hydrochlorothiazide 25 mg tablet, 100 *(Dithiazide)*

13475F **INDAPAMIDE**, indapamide hemihydrate 1.5 mg modified release tablet, 90 *(APO-Indapamide SR, Natrilix SR, Odaplix SR, Tenaxil SR)*

13378D **INDAPAMIDE**, indapamide hemihydrate 2.5 mg tablet, 90 *(Dapa-Tabs, Insig)*

13435D **IRBESARTAN**, irbesartan 75 mg tablet, 30 *(APO-Irbesartan, AVSARTAN, Abisart 75, Avapro, Blooms the Chemist Irbesartan, Irbesartan AMNEAL, Irbesartan AN, Irbesartan GH, Irbesartan Sandoz, Karvea, Noumed Irbesartan)*

13380F **IRBESARTAN**, irbesartan 150 mg tablet, 30 *(APO-Irbesartan, AVSARTAN, Abisart 150, Avapro, Blooms the Chemist Irbesartan, Irbesartan GH, Irbesartan Sandoz, Karvea, Noumed Irbesartan)*

13564X **IRBESARTAN**, irbesartan 300 mg tablet, 30 *(APO-Irbesartan, AVSARTAN, Abisart 300, Avapro, Blooms the Chemist Irbesartan, Irbesartan AN, Irbesartan GH, Irbesartan Sandoz, Karvea, Noumed Irbesartan)*

13572H **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Irbesartan HCTZ, AVSARTAN HCT 150/12.5, Abisart HCTZ 150/12.5, Avapro HCT 150/12.5, Blooms the Chemist Irbesartan HCTZ 150/12.5, Irbesartan/HCT Sandoz, Karvezide 150/12.5)*

13545X **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Irbesartan HCTZ, AVSARTAN HCT 300/12.5, Abisart HCTZ 300/12.5, Avapro HCT 300/12.5, Blooms the Chemist Irbesartan HCTZ 300/12.5, Irbesartan/HCT Sandoz, Karvezide 300/12.5)*

13446Q **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30 *(APO-Irbesartan HCTZ, AVSARTAN HCT 300/25, Abisart HCTZ 300/25, Avapro HCT 300/25, Blooms the Chemist Irbesartan HCTZ 300/25, Irbesartan/HCT Sandoz, Karvezide 300/25)*

13491C **ISOSORBIDE DINITRATE**, isosorbide dinitrate 5 mg sublingual tablet, 100 *(Isordil Sublingual)*

13461L **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 60 mg modified release tablet, 30 *(APO-Isosorbide Mononitrate, Duride, ISOBIDE MR, Imdur Durule, Isosorbide AN, Monodur 60 mg)*

13611J **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 120 mg modified release tablet, 30 *(Imdur 120 mg, Monodur 120 mg)*

13411W **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28 *(BTC Lercanidipine, Lercanidipine APOTEX, Zanidip, Zircol 10)*

13412X **LERCANIDIPINE**, lercanidipine hydrochloride 20 mg tablet, 28 *(BTC Lercanidipine, Lercanidipine APOTEX, Zanidip, Zircol 20)*

13507X **LERCANIDIPINE + ENALAPRIL**, lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28 *(Zan-Extra 10/10)*

13477H **LERCANIDIPINE + ENALAPRIL**, lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28 *(Zan-Extra 10/20)*

13583X **LISINOPRIL**, lisinopril 5 mg tablet, 30 *(APO-Lisinopril, Fibsol 5, Lisinopril Sandoz, Zestril, Zinopril 5)*

13584Y **LISINOPRIL**, lisinopril 10 mg tablet, 30 *(APO-Lisinopril, Fibsol 10, Lisinopril Sandoz, Zestril, Zinopril 10)*

13402J **LISINOPRIL**, lisinopril 20 mg tablet, 30 *(APO-Lisinopril, Fibsol 20, Lisinopril Sandoz, Lisinopril generichealth, Zestril, Zinopril 20)*

13361F **MESALAZINE**, mesalazine 500 mg modified release granules, 100 sachets *(Salofalk)*

13355X **MESALAZINE**, mesalazine 1 g modified release granules, 100 sachets *(Pentasa)*

13398E **MESALAZINE**, mesalazine 1 g modified release granules, 100 sachets *(Salofalk)*

13460K **MESALAZINE**, mesalazine 1.5 g modified release granules, 60 sachets *(Salofalk)*

13397D **MESALAZINE**, mesalazine 2 g modified release granules, 60 sachets *(Pentasa)*

13518L **MESALAZINE**, mesalazine 3 g modified release granules, 30 sachets *(Salofalk)*

13456F **MESALAZINE**, mesalazine 4 g modified release granules, 30 sachets *(Pentasa)*

13423L **MESALAZINE**, mesalazine 250 mg enteric tablet, 100 *(Mesasal)*

13362G **MESALAZINE**, mesalazine 500 mg enteric tablet, 100 *(Salofalk)*

13396C **MESALAZINE**, mesalazine 500 mg modified release tablet, 100 *(Pentasa)*

13422K **MESALAZINE**, mesalazine 800 mg enteric tablet, 90 *(Asacol)*

13394Y **MESALAZINE**, mesalazine 1 g enteric tablet, 60 *(Salofalk)*

13576M **MESALAZINE**, mesalazine 1 g modified release tablet, 60 *(Pentasa)*

13356Y **MESALAZINE**, mesalazine 1.2 g modified release tablet, 120 *(MESALZ)*

13487W **MESALAZINE**, mesalazine 1.2 g modified release tablet, 60 *(Mesalazine 1.2 TAKEDA, Mezavant)*

13395B **MESALAZINE**, mesalazine 1.6 g enteric tablet, 60 *(Asacol)*

13543T **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30 *(Metrol-XL 47.5, Minax XL, Topreloc-XL, Toprol-XL 47.5)*

13544W **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30 *(Metrol-XL 95, Minax XL, Topreloc-XL, Toprol-XL 95)*

13420H **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30 *(Metrol-XL 190, Minax XL, Topreloc-XL, Toprol-XL 190)*

13598Q **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100 *(APO-Metoprolol, Betaloc, Metoprolol Sandoz, Metrol 50, Minax 50, Mistrom, NOUMED METOPROLOL)*

13541Q **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60 *(APO-Metoprolol, Betaloc, Metoprolol Sandoz, Metrol 100, Minax 100, Mistrom, NOUMED METOPROLOL)*

13579Q **MOXONIDINE**, moxonidine 200 microgram tablet, 30 *(APO-Moxonidine, Moxonidine GH, Moxonidine GX, Moxonidine MYL, Moxonidine Viatris, Moxotens, Physiotens)*

13552G **MOXONIDINE**, moxonidine 400 microgram tablet, 30 *(APO-Moxonidine, Moxonidine GH, Moxonidine GX, Moxonidine MYL, Moxonidine Viatris, Moxotens, Physiotens)*

13617Q **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation *(Nyxoid (UK))*

13621X **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation *(Nyxoid (UK))*

13568D **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28 *(APO-Nebivolol, Nebilet, Nebivolol Lupin, Nebivolol Sandoz, Nepiten)*

13510C **NEBIVOLOL**, nebivolol 5 mg tablet, 28 *(APO-Nebivolol, Nebilet, Nebivolol Lupin, Nebivolol Sandoz, Nepiten)*

13441K **NEBIVOLOL**, nebivolol 10 mg tablet, 28 *(APO-Nebivolol, Nebilet, Nebivolol Lupin, Nebivolol Sandoz, Nepiten)*

13550E **NICORANDIL**, nicorandil 10 mg tablet, 60 *(APO-Nicorandil, Ikorel, Ikotab)*

13551F **NICORANDIL**, nicorandil 20 mg tablet, 60 *(APO-Nicorandil, Ikorel, Ikotab)*

13502P **NIFEDIPINE**, nifedipine 30 mg modified release tablet, 30 *(APO-Nifedipine XR, Addos XR 30)*

13376B **NIFEDIPINE**, nifedipine 60 mg modified release tablet, 30 *(APO-Nifedipine XR, Addos XR 60)*

13505T **OLMESARTAN**, olmesartan medoxomil 20 mg tablet, 30 *(APO-Olmesartan, APX-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan Sandoz, Olmetec, Olsetan, Pharmacor Olmesartan 20)*

13533G **OLMESARTAN**, olmesartan medoxomil 40 mg tablet, 30 *(APO-Olmesartan, APX-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan Sandoz, Olmetec, Olsetan, Pharmacor Olmesartan 40)*

13449W **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30 *(OLMEKAR, Olmesartan/Amlodipine - MYL 20/5, Olmesartan/Amlodipine 20/5 APOTEX, Pharmacor Olmesartan Amlodipine 20/5, Sevikar 20/5)*

13481M **OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5, Olamlo HCT 20/5/12.5, Olmekar HCT 20/5/12.5, Sevikar HCT 20/5/12.5)*

13512E **OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30 *(APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet, Olamlo HCT 40/5/25, Olmekar HCT 40/5/25, Sevikar HCT 40/5/25)*

13513F **OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet, Olamlo HCT 40/5/12.5, Olmekar HCT 40/5/12.5, Sevikar HCT 40/5/12.5)*

13482N **OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5, Olamlo HCT 40/10/12.5, Olmekar HCT 40/10/12.5, Sevikar HCT 40/10/12.5)*

13447R **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Olmesartan/HCTZ 20/12.5, APX-Olmesartan/HCTZ, OLMERTAN COMBI 20/12.5, Olmesartan HCT - MYL 20/12.5, Olmesartan/HCT Sandoz, Olmetec Plus, Pharmacor Olmesartan HCTZ 20/12.5)*

13601W **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30 *(APO-Olmesartan/HCTZ 40/12.5, APX-Olmesartan/HCTZ, OLMERTAN COMBI 40/12.5, Olmesartan HCT - MYL 40/12.5, Olmesartan/HCT Sandoz, Olmetec Plus, Pharmacor Olmesartan HCTZ 40/12.5)*

13602X **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30 *(APO-Olmesartan/HCTZ 40/25, APX-Olmesartan/HCTZ, OLMERTAN COMBI 40/25, Olmesartan HCT - MYL 40/25, Olmesartan/HCT Sandoz, Olmetec Plus, Pharmacor Olmesartan HCTZ 40/25)*

13560Q **PANCREATIC EXTRACT**, pancreatic extract 10 000 units modified release capsule, 100 *(Creon 10,000)*

13470Y **PANCREATIC EXTRACT**, pancreatic extract 25 000 units modified release capsule, 100 *(Creon 25,000)*

13407P **PANCREATIC EXTRACT**, pancreatic extract 35 000 units modified release capsule, 100 *(Creon 35,000)*

13375Y **PANCREATIC EXTRACT**, pancreatic extract 5000 units/100 mg enteric coated granules, 20 g *(Creon Micro)*

13609G **PATIROMER**, patiromer 8.4 g powder for oral liquid, 30 sachets *(Veltassa)*

13610H **PATIROMER**, patiromer 8.4 g powder for oral liquid, 30 sachets *(Veltassa)*

13613L **PATIROMER**, patiromer 16.8 g powder for oral liquid, 30 sachets *(Veltassa)*

13620W **PATIROMER**, patiromer 16.8 g powder for oral liquid, 30 sachets *(Veltassa)*

13458H **PENICILLAMINE**, penicillamine 125 mg tablet, 100 *(D-Penamine)*

13425N **PENICILLAMINE**, penicillamine 250 mg tablet, 100 *(D-Penamine)*

13404L **PERINDOPRIL**, perindopril erbumine 2 mg tablet, 30 *(APO-Perindopril, BTC Perindopril, Blooms the Chemist Perindopril, Idaprex 2, Indosyl Mono 2, PERISYL, Perindo)*

13494F **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30 *(APO-Perindopril Arginine, APX-Perindopril Arginine, Coversyl 2.5mg, PREXUM 2.5)*

13371R **PERINDOPRIL**, perindopril erbumine 4 mg tablet, 30 *(APO-Perindopril, BTC Perindopril, Blooms the Chemist Perindopril, Idaprex 4, Indosyl Mono 4, PERISYL, Perindo, Perindopril generichealth)*

13585B **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30 *(APO-Perindopril Arginine, APX-Perindopril Arginine, Coversyl 5mg, PREXUM 5)*

13372T **PERINDOPRIL**, perindopril erbumine 8 mg tablet, 30 *(APO-Perindopril, BTC Perindopril, Blooms the Chemist Perindopril, Idaprex 8, Indosyl Mono 8, PERISYL, Perindo, Perindopril generichealth)*

13555K **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30 *(APO-Perindopril Arginine, APX-Perindopril Arginine, Coversyl 10mg, PREXUM 10)*

13508Y **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30 *(APO-Perindopril Arginine/Amlodipine 5/5, APX-Perindopril Arginine/Amlodipine 5/5, Coveram 5/5, Reaptan 5/5)*

13381G **PERINDOPRIL + AMLODIPINE**, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30 *(APO-Perindopril Arginine/Amlodipine 5/10, APX-Perindopril Arginine/Amlodipine 5/10, Coveram 5/10, Reaptan 5/10)*

13478J **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30 *(APO-Perindopril Arginine/Amlodipine 10/5, APX-Perindopril Arginine/Amlodipine 10/5, Coveram 10/5, Reaptan 10/5)*

13382H **PERINDOPRIL + AMLODIPINE**, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30 *(APO-Perindopril Arginine/Amlodipine 10/10, APX-Perindopril Arginine/Amlodipine 10/10, Coveram 10/10, Reaptan 10/10)*

13413Y **PERINDOPRIL + INDAPAMIDE**, perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30 *(Coversyl Plus LD 2.5mg/0.625mg, PREXUM Combi LD 2.5/0.625)*

13476G **PERINDOPRIL + INDAPAMIDE**, perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30 *(APO-Perindopril/Indapamide, GenRx Perindopril/ Indapamide 4/1.25, Idaprex Combi 4/1.25, Indosyl Combi 4/1.25, PERISYL COMBI 4/1.25, Perindo Combi 4/1.25)*

13506W **PERINDOPRIL + INDAPAMIDE**, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30 *(Coversyl Plus 5mg/1.25mg, Prexum Combi 5/1.25)*

13357B **POTASSIUM CHLORIDE**, potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200 *(Span-K)*

13486T **POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**, potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60 *(Chlorvescent)*

13496H **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 10, Lipostat 10, Pravachol, Pravastatin Sandoz)*

13497J **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 20, Lipostat 20, Pravachol, Pravastatin Sandoz)*

13432Y **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 40, Lipostat 40, Pravachol, Pravastatin Sandoz)*

13527Y **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Lipostat 80, Pravachol)*

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

13400G **PRAZOSIN**, prazosin 2 mg tablet, 100 *(APO-Prazosin, Minipress)*

13367M **PRAZOSIN**, prazosin 5 mg tablet, 100 *(APO-Prazosin, Minipress)*

13386M **PROPRANOLOL**, propranolol hydrochloride 10 mg tablet, 100 *(APO-Propranolol, Deralin 10, Inderal)*

13542R **PROPRANOLOL**, propranolol hydrochloride 40 mg tablet, 100 *(APO-Propranolol, Deralin 40, Inderal)*

13426P **RALOXIFENE**, raloxifene hydrochloride 60 mg tablet, 28 *(APO-Raloxifene, Evista, Fixta 60, RALOVISTA, Raloxifene GH)*

13431X **RAMIPRIL**, ramipril 1.25 mg capsule, 30 *(APO-Ramipril, Tryzan Caps 1.25)*

13405M **RAMIPRIL**, ramipril 2.5 mg capsule, 30 *(APO-Ramipril, Tryzan Caps 2.5)*

13556L **RAMIPRIL**, ramipril 5 mg capsule, 30 *(APO-Ramipril, Tryzan Caps 5)*

13430W **RAMIPRIL**, ramipril 10 mg capsule, 30 *(APO-Ramipril, APX-Ramipril, Prilace, Ramipril Sandoz, Ramipril Winthrop, Tritace 10 mg, Tryzan Caps 10)*

13582W **RAMIPRIL**, ramipril 1.25 mg tablet, 30 *(Prilace, Ramipril Sandoz, Ramipril Winthrop, Tritace 1.25 mg, Tryzan Tabs 1.25)*

13466R **RAMIPRIL**, ramipril 2.5 mg tablet, 30 *(APO-Ramipril, Prilace, Ramipril Sandoz, Ramipril Winthrop, Tritace 2.5 mg, Tryzan Tabs 2.5)*

13526X **RAMIPRIL**, ramipril 5 mg tablet, 30 *(APO-Ramipril, Prilace, Ramipril Sandoz, Ramipril Winthrop, Tritace 5 mg, Tryzan Tabs 5)*

13368N **RAMIPRIL**, ramipril 10 mg tablet, 30 *(APO-Ramipril, Ramipril Sandoz, Tritace, Tryzan Tabs 10)*

13563W **RAMIPRIL + FELODIPINE**, ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30 *(Triasyn 2.5/2.5)*

13534H **RAMIPRIL + FELODIPINE**, ramipril 5 mg + felodipine 5 mg modified release tablet, 30 *(Triasyn 5.0/5.0)*

13360E **RISEDRONATE**, risedronate sodium 5 mg tablet, 28 *(Actonel)*

13364J **RISEDRONATE**, risedronate sodium 35 mg enteric tablet, 4 *(Actonel EC)*

13459J **RISEDRONATE**, risedronate sodium 35 mg tablet, 4 *(APO-Risedronate, Risedronate Sandoz)*

13488X **RISEDRONATE**, risedronate sodium 150 mg tablet, 1 *(APO-Risedronate, Actonel Once-a-Month)*

13366L **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60 *(Xarelto)*

13521P **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30 *(Xarelto)*

13463N **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28 *(Xarelto)*

13462M **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28 *(Xarelto)*

13406N **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30 *(APX-Rosuvastatin, Blooms Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 5, Noumed Rosuvastatin, Pharmacor Rosuvastatin 5, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

13586C **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30 *(APX-Rosuvastatin, Blooms Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 10, Noumed Rosuvastatin, Pharmacor Rosuvastatin 10, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

13588E **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30 *(APX-Rosuvastatin, Blooms Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 20, Noumed Rosuvastatin, Pharmacor Rosuvastatin 20, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

13589F **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30 *(APX-Rosuvastatin, Blooms Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 40, Noumed Rosuvastatin, Pharmacor Rosuvastatin 40, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

13570F **SACUBITRIL + VALSARTAN**, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56 *(Entresto)*

13511D **SACUBITRIL + VALSARTAN**, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56 *(Entresto)*

13445P **SACUBITRIL + VALSARTAN**, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56 *(Entresto)*

13559P **SIMVASTATIN**, simvastatin 5 mg tablet, 30 *(Simvastatin Sandoz, Zimstat)*

13528B **SIMVASTATIN**, simvastatin 10 mg tablet, 30 *(APO-Simvastatin, NOUMED SIMVASTATIN, Simvar 10, Simvastatin Sandoz, Zimstat)*

13373W **SIMVASTATIN**, simvastatin 20 mg tablet, 30 *(APO-Simvastatin, Lipex 20, NOUMED SIMVASTATIN, Simvar 20, Simvastatin Sandoz, Zimstat, Zocor)*

13471B **SIMVASTATIN**, simvastatin 40 mg tablet, 30 *(APO-Simvastatin, Lipex 40, NOUMED SIMVASTATIN, Simvar 40, Simvastatin Sandoz, Zimstat, Zocor)*

13498K **SIMVASTATIN**, simvastatin 80 mg tablet, 30 *(APO-Simvastatin, Simvar 80, Simvastatin Sandoz, Zimstat)*

13503Q **SPIRONOLACTONE**, spironolactone 25 mg tablet, 100 *(Aldactone, Spiractin 25, Spironolactone Viatris 25)*

13433B **SULFASALAZINE**, sulfasalazine 500 mg enteric tablet, 100 *(Pyralin EN, Salazopyrin-EN)*

13557M **SULFASALAZINE**, sulfasalazine 500 mg tablet, 100 *(Salazopyrin)*

13437F **TELMISARTAN**, telmisartan 40 mg tablet, 28 *(APO-Telmisartan, Micardis, Mizart, NOUMED TELMISARTAN, Pharmacor Telmisartan 40, Telmisartan Sandoz, Telmisartan-DRLA, Teltartan)*

13593K **TELMISARTAN**, telmisartan 80 mg tablet, 28 *(APO-Telmisartan, Micardis, Mizart, NOUMED TELMISARTAN, Pharmacor Telmisartan 80, Telmisartan Sandoz, Telmisartan-DRLA, Teltartan)*

13483P **TELMISARTAN + AMLODIPINE**, telmisartan 40 mg + amlodipine 5 mg tablet, 28 *(Pritor/Amlodipine, Twynsta)*

13515H **TELMISARTAN + AMLODIPINE**, telmisartan 40 mg + amlodipine 10 mg tablet, 28 *(Pritor/Amlodipine, Twynsta)*

13450X **TELMISARTAN + AMLODIPINE**, telmisartan 80 mg + amlodipine 5 mg tablet, 28 *(Pritor/Amlodipine, Twynsta)*

13451Y **TELMISARTAN + AMLODIPINE**, telmisartan 80 mg + amlodipine 10 mg tablet, 28 *(Pritor/Amlodipine, Twynsta)*

13546Y **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(APO-Telmisartan HCTZ 40/12.5, Micardis Plus 40/12.5 mg, Mizart HCT 40/12.5 mg, Telmisartan/HCT Sandoz, Teltartan HCT 40/12.5)*

13574K **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(APO-Telmisartan HCTZ 80/12.5, Micardis Plus 80/12.5 mg, Mizart HCT 80/12.5 mg, Telmisartan/HCT Sandoz, Teltartan HCT 80/12.5)*

13607E **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28 *(APO-Telmisartan HCTZ 80/25, Micardis Plus 80/25 mg, Mizart HCT 80/25 mg, Telmisartan HCT GH 80/25, Telmisartan/HCT Sandoz, Teltartan HCT 80/25)*

13354W **THIAMINE**, thiamine hydrochloride 100 mg tablet, 100 *(Betavit)*

13524T **TICAGRELOR**, ticagrelor 90 mg tablet, 56 *(Brilinta)*

13554J **TRANDOLAPRIL**, trandolapril 500 microgram capsule, 28 *(Dolapril 0.5, Gopten, Tranalpha)*

13429T **TRANDOLAPRIL**, trandolapril 1 mg capsule, 28 *(Dolapril 1, Gopten, Tranalpha)*

13403K **TRANDOLAPRIL**, trandolapril 2 mg capsule, 28 *(Dolapril 2, Gopten, Tranalpha)*

13467T **TRANDOLAPRIL**, trandolapril 4 mg capsule, 28 *(Dolapril 4, Gopten, Tranalpha)*

13594L **TRANDOLAPRIL + VERAPAMIL**, trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28 *(Tarka 2/180)*

13591H **TRANDOLAPRIL + VERAPAMIL**, trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28 *(Tarka 4/240)*

13414B **VALSARTAN**, valsartan 80 mg tablet, 28 *(Dilart, Diovan)*

13566B **VALSARTAN**, valsartan 160 mg tablet, 28 *(Dilart, Diovan)*

13383J **VALSARTAN**, valsartan 320 mg tablet, 28 *(Dilart, Diovan)*

13393X **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(Co-Diovan 80/12.5, Dilart HCT 80/12.5)*

13606D **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(Co-Diovan 160/12.5, Dilart HCT 160/12.5)*

13453C **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 *(Co-Diovan 160/25, Dilart HCT 160/25)*

13517K **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28 *(Co-Diovan 320/12.5, Dilart HCT 320/12.5)*

13455E **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 *(Co-Diovan 320/25, Dilart HCT 320/25)*

13530D **VERAPAMIL**, verapamil hydrochloride 80 mg tablet, 100 *(Anpec 80, Isoptin)*

13434C **VERAPAMIL**, verapamil hydrochloride 180 mg modified release tablet, 30 *(Cordilox 180 SR, Isoptin 180 SR)*

13408Q **VERAPAMIL**, verapamil hydrochloride 240 mg modified release tablet, 30 *(Cordilox SR, Isoptin SR)*

13616P **ZANUBRUTINIB**, zanubrutinib 80 mg capsule, 120 *(Brukinsa)*

13628G **ZANUBRUTINIB**, zanubrutinib 80 mg capsule, 120 *(Brukinsa)*

### *Addition – Brand*

11941L *Alphaclav Duo Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

1891M *Alphaclav Duo Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

5008N *Alphaclav Duo Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

11933C *Alphaclav Duo Forte Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

5006L *Alphaclav Duo Forte Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K *Alphaclav Duo Forte Viatris, AL* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

3145M *Clonidine Lupin, GQ* – **CLONIDINE**, clonidine hydrochloride 100 microgram tablet, 100

9432K *LoxaLate, AF* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

5262Y *Fingolimod Sandoz, SZ* – **FINGOLIMOD**, fingolimod 500 microgram capsule, 28

2174K *APO-Levothyroxine, XT* – **LEVOTHYROXINE**, levothyroxine sodium 50 microgram tablet, 200

2174K *Levothyroxine Lup, GQ* – **LEVOTHYROXINE**, levothyroxine sodium 50 microgram tablet, 200

9287T *APO-Levothyroxine, XT* – **LEVOTHYROXINE**, levothyroxine sodium 75 microgram tablet, 200

9287T *Levothyroxine Lup, GQ* – **LEVOTHYROXINE**, levothyroxine sodium 75 microgram tablet, 200

2175L *APO-Levothyroxine, XT* – **LEVOTHYROXINE**, levothyroxine sodium 100 microgram tablet, 200

2175L *Levothyroxine Lup, GQ* – **LEVOTHYROXINE**, levothyroxine sodium 100 microgram tablet, 200

2173J *APO-Levothyroxine, XT* – **LEVOTHYROXINE**, levothyroxine sodium 200 microgram tablet, 200

2173J *Levothyroxine Lup, GQ* – **LEVOTHYROXINE**, levothyroxine sodium 200 microgram tablet, 200

3132W *Alepam 15, AF* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

3134Y *Alepam 15, AF* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

5192G *Alepam 15, AF* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

3133X *Alepam 30, AF* – **OXAZEPAM**, oxazepam 30 mg tablet, 25

3135B *Alepam 30, AF* – **OXAZEPAM**, oxazepam 30 mg tablet, 25

5193H *Alepam 30, AF* – **OXAZEPAM**, oxazepam 30 mg tablet, 25

2606E *Blooms Rosuvastatin, BG* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2628H *Blooms Rosuvastatin, BG* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2574L *Blooms Rosuvastatin, BG* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2594M *Blooms Rosuvastatin, BG* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

### *Addition – Equivalence Indicator*

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

2928D *Alfamino, NT* – **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**, amino acid synthetic formula

supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

1449G *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

5105Q *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

11816X *Nyxoid, MF* – **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

11817Y *Nyxoid, MF* – **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

3132W *Serepax, AS* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

3134Y *Serepax, AS* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

5192G *Serepax, AS* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

### *Addition – Note*

1449G **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

5105Q **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

11213E **IBRUTINIB**, ibrutinib 140 mg capsule, 90 *(Imbruvica)*

11816X **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation *(Nyxoid)*

11817Y **NALOXONE**, naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation *(Nyxoid)*

11630D **VENETOCLAX**, venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack *(Venclexta)*

## Deletions

### *Deletion – Item*

12320K **APOMORPHINE**, apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules *(Movapo)*

1818Q **METHOTREXATE**, methotrexate 50 mg/2 mL injection, 2 mL vial *(Methotrexate Accord)*

8410P **ONDANSETRON**, ondansetron 4 mg wafer, 4 *(Zofran Zydis)*

### *Deletion – Brand*

9012H *FonatPlus, AF* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

9183H *FonatPlus, AF* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

8179L *Anastrozole FBM, FO* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30

8717T *Aripiprazole generichealth, HQ* – **ARIPIPRAZOLE**, aripiprazole 10 mg tablet, 30

8718W *Aripiprazole generichealth, HQ* – **ARIPIPRAZOLE**, aripiprazole 15 mg tablet, 30

8719X *Aripiprazole generichealth, HQ* – **ARIPIPRAZOLE**, aripiprazole 20 mg tablet, 30

10131F *Everolimus Sandoz, SZ* – **EVEROLIMUS**, everolimus 5 mg tablet, 30

11362B *Everolimus Sandoz, SZ* – **EVEROLIMUS**, everolimus 5 mg tablet, 30

10135K *Everolimus Sandoz, SZ* – **EVEROLIMUS**, everolimus 10 mg tablet, 30

11377T *Everolimus Sandoz, SZ* – **EVEROLIMUS**, everolimus 10 mg tablet, 30

10915L *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10918P *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10920R *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10924Y *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10940T *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10941W *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

10942X *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11757T *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11770L *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11776T *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11777W *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11782D *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11783E *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

11875B *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

12709X *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

12710Y *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

12722N *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

12759M *Imatinib GH, GQ* – **IMATINIB**, imatinib 100 mg capsule, 60

8245Y *Letrozole FBM, FO* – **LETROZOLE**, letrozole 2.5 mg tablet, 30

12830G *Levothox, AF* – **LEVOTHYROXINE**, levothyroxine sodium 125 microgram tablet, 200

5470X *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 4

5471Y *Ondansetron ODT Lupin, HQ* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4

### *Deletion – Equivalence Indicator*

13347L *JAMP-Cholestyramine, DZ* – **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets

13351Q *JAMP-Cholestyramine, DZ* – **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets

2967E *Questran Lite, GO* – **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 50 sachets

9249T *Questran Lite, GO* – **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 50 sachets

10131F *Afinitor, NV* – **EVEROLIMUS**, everolimus 5 mg tablet, 30

11362B *Afinitor, NV* – **EVEROLIMUS**, everolimus 5 mg tablet, 30

10135K *Afinitor, NV* – **EVEROLIMUS**, everolimus 10 mg tablet, 30

11377T *Afinitor, NV* – **EVEROLIMUS**, everolimus 10 mg tablet, 30

12830G *Eltroxin, LT* – **LEVOTHYROXINE**, levothyroxine sodium 125 microgram tablet, 200

2395C *DBL Methotrexate, PF* – **METHOTREXATE**, methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

### *Deletion – Note*

13347L **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets *(JAMP-Cholestyramine)*

13351Q **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets *(JAMP-Cholestyramine)*

2967E **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 50 sachets *(Questran Lite)*

9249T **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 50 sachets *(Questran Lite)*

2395C **METHOTREXATE**, methotrexate 50 mg/2 mL injection, 5 x 2 mL vials *(DBL Methotrexate)*

5470X **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 4 *(APO-Ondansetron ODT, APX-Ondansetron ODT, Ondansetron AN ODT, Ondansetron Mylan ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Zotren ODT)*

5471Y **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4 *(APO-Ondansetron ODT, APX-Ondansetron ODT, Ondansetron AN ODT, Ondansetron Mylan ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Zotren ODT)*

8411Q **ONDANSETRON**, ondansetron 8 mg wafer, 4 *(Zofran Zydis)*

## Alterations

### *Alteration – Authorised Prescriber*

| | | *From* | *To* |
|---|---|---|---|
| 10211K | **MIFEPRISTONE (&) MISOPROSTOL**, mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack *(MS-2 Step)* | M,N | M,N,W |

### *Alteration – Note*

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

13318Y **ACALABRUTINIB**, acalabrutinib 100 mg tablet, 56 *(CALQUENCE)*

11301T **BUDESONIDE + FORMOTEROL**, budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations *(BiResp Spiromax, DuoResp Spiromax)*

13258T **BUDESONIDE + FORMOTEROL**, budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations *(DuoResp Spiromax, Rilast TURBUHALER 400/12, Symbicort TURBUHALER 400/12)*

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

12969N **LEVOTHYROXINE**, levothyroxine sodium 50 microgram tablet, 2 x 100 *(LEVOXINE)*

2174K **LEVOTHYROXINE**, levothyroxine sodium 50 microgram tablet, 200 *(APO-Levothyroxine, Eltroxin, Eutroxsig, Levothox, Levothyroxine Lup, Oroxine)*

12960D **LEVOTHYROXINE**, levothyroxine sodium 75 microgram tablet, 2 x 100 *(LEVOXINE)*

9287T **LEVOTHYROXINE**, levothyroxine sodium 75 microgram tablet, 200 *(APO-Levothyroxine, Eltroxin, Eutroxsig, Levothox, Levothyroxine Lup, Oroxine)*

12968M **LEVOTHYROXINE**, levothyroxine sodium 100 microgram tablet, 2 x 100 *(LEVOXINE)*

2175L **LEVOTHYROXINE**, levothyroxine sodium 100 microgram tablet, 200 *(APO-Levothyroxine, Eltroxin, Eutroxsig, Levothox, Levothyroxine Lup, Oroxine)*

12970P **LEVOTHYROXINE**, levothyroxine sodium 200 microgram tablet, 2 x 100 *(LEVOXINE)*

2173J **LEVOTHYROXINE**, levothyroxine sodium 200 microgram tablet, 200 *(APO-Levothyroxine, Eltroxin, Eutroxsig, Levothox, Levothyroxine Lup, Oroxine)*

12188L **VENETOCLAX**, venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack *(Venclexta)*

12999E **VENETOCLAX**, venetoclax 10 mg tablet, 2 *(Venclexta)*

11648C **VENETOCLAX**, venetoclax 50 mg tablet, 7 *(Venclexta)*

11639N **VENETOCLAX**, venetoclax 100 mg tablet, 120 *(Venclexta)*

12199C **VENETOCLAX**, venetoclax 100 mg tablet, 120 *(Venclexta)*

12205J **VENETOCLAX**, venetoclax 100 mg tablet, 120 *(Venclexta)*

### *Alteration – Restriction*

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

13318Y **ACALABRUTINIB**, acalabrutinib 100 mg tablet, 56 *(CALQUENCE)*

11213E **IBRUTINIB**, ibrutinib 140 mg capsule, 90 *(Imbruvica)*

11170X **IDELALISIB**, idelalisib 100 mg tablet, 60 *(Zydelig)*

11162L **IDELALISIB**, idelalisib 150 mg tablet, 60 *(Zydelig)*

13345J **TOFACITINIB**, tofacitinib 5 mg tablet, 56 *(Xeljanz)*

11630D **VENETOCLAX**, venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack *(Venclexta)*

12188L **VENETOCLAX**, venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack *(Venclexta)*

### *Alteration – Manufacturer Code*

| | | *From* | *To* |
|---|---|---|---|
| 1195X | *Largactil* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules | SW | IX |
| 1201F | *Largactil* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL | SW | IX |
| 1197B | *Largactil* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 25 mg tablet, 100 | SW | IX |
| 1199D | *Largactil* – **CHLORPROMAZINE**, chlorpromazine hydrochloride 100 mg tablet, 100 | SW | IX |
| 3052P | *Neulactil* – **PERICIAZINE**, periciazine 2.5 mg tablet, 100 | SW | IX |
| 3053Q | *Neulactil* – **PERICIAZINE**, periciazine 10 mg tablet, 100 | SW | IX |

## Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.

Further information on Supply Only arrangements is available at www.pbs.gov.au

***Supply Only Commencing 1 September 2023***

9230T **ATORVASTATIN**, atorvastatin 10 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 10, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

9231W **ATORVASTATIN**, atorvastatin 20 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 20, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

9232X **ATORVASTATIN**, atorvastatin 40 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 40, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

9233Y **ATORVASTATIN**, atorvastatin 80 mg tablet, 30 *(APO-Atorvastatin, Atorvachol, Atorvastatin GH, Atorvastatin SZ, Blooms the Chemist Atorvastatin, Lipitor, Lorstat 80, NOUMED ATORVASTATIN, Pharmacor Atorvastatin, Trovas)*

9246P **FENOFIBRATE**, fenofibrate 48 mg tablet, 60 *(APO-Fenofibrate, FENOFIBRATE RBX, Fenofibrate Cipla, Fenofibrate Mylan, Fenofibrate Viatris, Lipidil)*

9247Q **FENOFIBRATE**, fenofibrate 145 mg tablet, 30 *(APO-Fenofibrate, Blooms the Chemist Fenofibrate, FENOFIBRATE RBX, Fenocol, Fenofibrate Cipla, Fenofibrate Mylan, Fenofibrate Sandoz, Fenofibrate Viatris, Lipidil)*

9236D **FLUVASTATIN**, fluvastatin 80 mg modified release tablet, 28 *(Lescol XL)*

9248R **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60 *(Ausgem, Lipigem)*

9226N **PANCREATIC EXTRACT**, pancreatic extract 10 000 units modified release capsule, 100 *(Creon 10,000)*

9227P **PANCREATIC EXTRACT**, pancreatic extract 25 000 units modified release capsule, 100 *(Creon 25,000)*

12578B **PANCREATIC EXTRACT**, pancreatic extract 35 000 units modified release capsule, 100 *(Creon 35,000)*

5454C **PANCREATIC EXTRACT**, pancreatic extract 5000 units/100 mg enteric coated granules, 20 g *(Creon Micro)*

9237E **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 10, Lipostat 10, Pravachol, Pravastatin Sandoz)*

9238F **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 20, Lipostat 20, Pravachol, Pravastatin Sandoz)*

9239G **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Cholstat 40, Lipostat 40, Pravachol, Pravastatin Sandoz)*

9240H **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30 *(APO-Pravastatin, APX-Pravastatin, Lipostat 80, Pravachol)*

2590H **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30 *(APX-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 5, Noumed Rosuvastatin, Pharmacor Rosuvastatin 5, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

2584B **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30 *(APX-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 10, Noumed Rosuvastatin, Pharmacor Rosuvastatin 10, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

2609H **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30 *(APX-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 20, Noumed Rosuvastatin, Pharmacor Rosuvastatin 20, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

2636R **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30 *(APX-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Crestor, Crosuva 40, Noumed Rosuvastatin, Pharmacor Rosuvastatin 40, Rosuvastatin APOTEX, Rosuvastatin Lupin, Rosuvastatin RBX, Rosuvastatin Sandoz)*

9241J **SIMVASTATIN**, simvastatin 5 mg tablet, 30 *(Simvastatin Sandoz, Zimstat)*

9242K **SIMVASTATIN**, simvastatin 10 mg tablet, 30 *(APO-Simvastatin, NOUMED SIMVASTATIN, Simvar 10, Simvastatin Sandoz, Zimstat)*

9243L **SIMVASTATIN**, simvastatin 20 mg tablet, 30 *(APO-Simvastatin, Lipex 20, NOUMED SIMVASTATIN, Simvar 20, Simvastatin Sandoz, Zimstat, Zocor)*

9244M **SIMVASTATIN**, simvastatin 40 mg tablet, 30 *(APO-Simvastatin, Lipex 40, NOUMED SIMVASTATIN, Simvar 40, Simvastatin Sandoz, Zimstat, Zocor)*

9245N **SIMVASTATIN**, simvastatin 80 mg tablet, 30 *(APO-Simvastatin, Simvar 80, Simvastatin Sandoz, Zimstat)*

9208P **SULFASALAZINE**, sulfasalazine 500 mg tablet, 100 *(Salazopyrin)*

9209Q **SULFASALAZINE**, sulfasalazine 500 mg enteric tablet, 100 *(Pyralin EN, Salazopyrin-EN)*

## Advance Notices

***1 October 2023***
***Deletion – Brand***

9012H *ALENDRONATE PLUS D3 70mg/70ug APOTEX, GX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

9183H *ALENDRONATE PLUS D3 70mg/140ug APOTEX, GX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

9022W *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 48 mg tablet, 60

9023X *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 145 mg tablet, 30

5264C *Methylprednisolone Alphapharm, AF* – **METHYLPREDNISOLONE**, methylprednisolone 1 g injection, 1 vial

9019Q *Moxonidine MYL, AF* – **MOXONIDINE**, moxonidine 200 microgram tablet, 30

11798Y *Jetrea RTU, IJ* – **OCRIPLASMIN**, ocriplasmin 375 microgram/0.3 mL intraocular injection, 0.3 mL vial

11683X *Omeprazole generichealth, GQ* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

12272X *Omeprazole generichealth, GQ* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

8331L *Omeprazole generichealth, GQ* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

8333N *Omeprazole generichealth, GQ* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

1968N *Qpril 5, AF* – **QUINAPRIL**, quinapril 5 mg tablet, 30

1969P *Qpril 10, AF* – **QUINAPRIL**, quinapril 10 mg tablet, 30

1970Q *Qpril 20, AF* – **QUINAPRIL**, quinapril 20 mg tablet, 30

9381R *Telmisartan HCT GH 80/25, GQ* – **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

***1 November 2023***
***Deletion – Brand***

2363J *Pregabalin GH, GQ* – **PREGABALIN**, pregabalin 300 mg capsule, 56

***1 December 2023***
***Deletion – Brand***

8596K *Amisulpride 400 Winthrop, WA* – **AMISULPRIDE**, amisulpride 400 mg tablet, 60

2418G *Amitriptyline Alphapharm 25, MQ* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50

8452W *Amaryl, SW* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

9020R *Moxonidine MYL, AF* – **MOXONIDINE**, moxonidine 400 microgram tablet, 30

8228C *Ikorel, SW* – **NICORANDIL**, nicorandil 10 mg tablet, 60

8229D *Ikorel, SW* – **NICORANDIL**, nicorandil 20 mg tablet, 60

8411Q *Zofran Zydis, AS* – **ONDANSETRON**, ondansetron 8 mg wafer, 4

***1 January 2024***
***Deletion – Brand***

10062N *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

2438H *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

8381D *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 250 mg capsule, 5

# Palliative Care

## Additions

***Addition – Brand***

5371Q *Alepam 15, AF* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

5372R *Alepam 30, AF* – **OXAZEPAM**, oxazepam 30 mg tablet, 25

***Addition – Equivalence Indicator***

5371Q *Serepax, AS* – **OXAZEPAM**, oxazepam 15 mg tablet, 25

# Highly Specialised Drugs Program (Private Hospital)

## Additions

***Addition – Caution***

12784W **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

## Deletions

***Deletion – Item***

9607P **APOMORPHINE**, apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules *(Movapo)*

## Alterations

***Alteration – Caution***

13033Y **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13038F **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13039G **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13040H **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

6100C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

6138C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

## Advance Notices

***1 October 2023***
***Deletion – Brand***

11420C *Bacthecal, DZ* – **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

6227R *Octreotide MaxRx, GQ* – **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

***1 November 2023***
***Deletion – Brand***

6357N *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

***1 December 2023***
***Deletion – Brand***

6126K *Neupogen, AN* – **FILGRASTIM**, filgrastim 300 microgram/mL injection, 10 x 1 mL vials

6127L *Neupogen, AN* – **FILGRASTIM**, filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

6291D *Neupogen, AN* – **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E *Neupogen, AN* – **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6229W *Octreotide MaxRx, GQ* – **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

# Highly Specialised Drugs Program (Public Hospital)

## Additions

***Addition – Caution***

12771E **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

## Deletions

***Deletion – Item***

5609F **APOMORPHINE**, apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules *(Movapo)*

## Alterations

***Alteration – Caution***

13028Q **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13036D **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13042K **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

13044M **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

9597D **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

9598E **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Juno, Azacitidine MSN, Azacitidine Sandoz, Azacitidine-Teva)*

## Advance Notices

***1 October 2023***
***Deletion – Brand***

11421D *Bacthecal, DZ* – **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

9508K *Octreotide MaxRx, GQ* – **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

***1 November 2023***
***Deletion – Brand***

9569P *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

***1 December 2023***
***Deletion – Brand***

5741E *Neupogen, AN* – **FILGRASTIM**, filgrastim 300 microgram/mL injection, 10 x 1 mL vials

5742F *Neupogen, AN* – **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5743G *Neupogen, AN* – **FILGRASTIM**, filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

5744H *Neupogen, AN* – **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9510M *Octreotide MaxRx, GQ* – **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

# Highly Specialised Drugs Program (Community Access)

## Deletions

***Deletion – Item***

10335Y **SAQUINAVIR**, saquinavir 500 mg tablet, 120 *(Invirase)*

***Deletion – Brand***

10353X *Entecavir GH, GQ* – **ENTECAVIR**, entecavir 1 mg tablet, 30

## Advance Notices

***1 November 2023***
***Deletion – Brand***

10306K *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

# Repatriation Pharmaceutical Benefits

## Deletions

***Deletion – Brand***

2194L *FonatPlus, AF* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

2224C *FonatPlus, AF* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

## Advance Notices

***1 October 2023***

***Deletion – Brand***

2194L *ALENDRONATE PLUS D3 70mg/70ug APOTEX, GX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

2224C *ALENDRONATE PLUS D3 70mg/140ug APOTEX, GX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

# About the Schedule

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

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

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

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

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

## Symbols and Abbreviations Used in the Schedule

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

# Restricted Benefits

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

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

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

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

# Guidelines and General Statements

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

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

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

**Treatment criteria:**

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

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

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

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

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

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

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

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

***HEPATITIS C – CIRRHOTIC PATIENTS***

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

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

- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

3. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.

4. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.

5. GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:

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

# Pharmaceutical Benefits Schedules

# Prescriber Bag

## ▪ ADRENALINE (EPINEPHRINE)

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3451P | 1 | 20.63 | Link Medical Products Pty Ltd [LM] |

NP

## ▪ ATROPINE SULFATE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3453R | 1 | 24.66 | Pfizer Australia Pty Ltd [PF] |

NP

## ▪ BENZATHINE BENZYLPENICILLIN

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 11755Q | 1 | 305.73 | Bicillin L-A [PF] |

NP

## ▪ BENZATROPINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 11265X | 1 | 118.14 | Benzatropine Injection [FF] |

NP

## ▪ BENZYLPENICILLIN

**benzylpenicillin 600 mg injection, 1 vial**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3486L | 5 | *42.67 | BenPen [CS] |

NP

**OR**

## ▪ PROCAINE BENZYLPENICILLIN

**procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3485K | 1 | 62.27 | Cilicaine [AF] |

NP

## ▪ BENZYLPENICILLIN

**benzylpenicillin 3 g injection, 1 vial**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3487M | 1 | 22.57 | BenPen [CS] |

NP

## ▪ CHLORPROMAZINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3455W | 1 | 22.91 | Largactil [IX] |

NP

**OR**

## ▪ HALOPERIDOL

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3456X | 1 | 24.19 | Serenace [AS] |

NP

## ▪ CLONAZEPAM

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3478C | ‡1 | 16.75 | Rivotril [PB] |

NP

## ▪ DIPHTHERIA + TETANUS VACCINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3463G | 2 | *130.71 | ADT Booster [CS] |

NP

## ▪ FUROSEMIDE

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

3466K NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 16.11 | Lasix [SW] |

## ▪ FUROSEMIDE

**furosemide 20 mg tablet, 50**

12222G NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| 1 | 15.68 | [a] Frusemix-M [TY] | [a] Urex-M [RW] |

## ▪ GLUCAGON HYDROCHLORIDE

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

13625D NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 91.98 | [a] GlucaGen Hypokit (Germany) [DZ] |

**OR**

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

3467L NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 50.63 | [a] GlucaGen Hypokit [NO] |

## ▪ GLYCERYL TRINITRATE

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

3475X NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| ‡1 | 24.91 | Nitrolingual Pumpspray [SW] |

## ▪ HYDROCORTISONE SODIUM SUCCINATE

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

3470P NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 2 | *22.79 | Solu-Cortef [PF] |

**OR**

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

3471Q NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 21.75 | Solu-Cortef [PF] |

## ▪ HYOSCINE BUTYLBROMIDE

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

3473T NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| 1 | 20.05 | [a] Buscopan [VZ] | [a] HYOSCINE BUTYLBROMIDE-AFT [AE] |
| | | [a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ] | [a] HYOSCINE BUTYLBROMIDE SXP [XN] |

## ▪ LIDOCAINE

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

10209H NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 40.52 | Pfizer Australia Pty Ltd [PF] |

## ▪ METHOXYFLURANE

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

3489P

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 53.97 | Penthrox [DV] |

## ▪ METOCLOPRAMIDE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3476Y | | | |
| NP | 1 | 16.59 | Maxolon [IL] |

**OR**

## ▪ PROCHLORPERAZINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3477B | | | |
| NP | 1 | 22.67 | Stemetil [SW] |

## ▪ MIDAZOLAM

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10178Q | | | |
| NP | 1 | 40.76 | Pfizer Australia Pty Ltd [PF] |

## ▪ MOLNUPIRAVIR

**molnupiravir 200 mg capsule, 40**

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 13144T | | | |
| NP | 2 | *2192.27 | Lagevrio [MK] |

## ▪ MORPHINE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10862Q | | | |
| NP | 1 | 22.92 | Morphine Juno [JU] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 10868B | | | |
| NP | 1 | 25.45 | Morphine Juno [JU] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3479D | | | |
| NP | 1 | 24.21 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 3480E | | | |
| NP | 1 | 25.86 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

## ▪ NALOXONE

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|
| 10786Q | | | | |
| NP | 2 | *57.21 | [a] Naloxone Hydrochloride (DBL) [PF]<br>[a] NALOXONE SXP [XN] | [a] Naloxone Juno [JU] |

**OR**

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 11233F | | | |
| NP | 1 | 57.20 | NARCAN [FF] |

## ▪ NIRMATRELVIR (&) RITONAVIR

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

| | Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|---|
| 13147Y | | | |
| NP | 2 | *2216.27 | Paxlovid [HD] |

## ▪ PHYTOMENADIONE

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

10213M

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 1 | 25.81 | Konakion MM [PB] |

## ▪ PROMETHAZINE

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

3488N

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| 2 | *31.33 | DBL Promethazine Hydrochloride [PF] |

## ▪ SALBUTAMOL

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

11088N

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| ‡1 | 18.00 | Ventolin Nebules [GK] |

**OR**

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

3497C

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| ‡1 | 17.20 | [a] Salbutamol AN [ED] | [a] Salbutamol Cipla [LR] |

## ▪ SALBUTAMOL

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

11125M

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| ‡1 | 17.87 | Ventolin Nebules [GK] |

**OR**

**salbutamol 100 microgram/actuation inhalation, 200 actuations**

12108G

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| ‡1 | 18.28 | [a] Zempreon CFC-Free with dose counter [AL] |
| | 19.28 | [a] Asmol CFC-Free with dose counter [AF] |
| | 20.79 | [a] Ventolin CFC-Free with dose counter [GK] |

**OR**

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

3496B

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer |
|---|---|---|
| ‡1 | 16.99 | Salbutamol Cipla [LR] |

## ▪ TRAMADOL

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

3484J

NP

| Max.Qty Packs | DPMQ $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|
| 1 | 16.55 | [a] Tramadol AN [JU] | [a] Tramadol Sandoz [SZ] |
| | | [a] Tramal 100 [CS] | |

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# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### AMPHOTERICIN B

**amphotericin B 10 mg lozenge, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2931G NP | 1 | 1 | .. | 17.36 | 18.76 | Fungilin [AS] |

**amphotericin B 10 mg lozenge, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3306B DP | 1 | .. | .. | 17.36 | 18.76 | Fungilin [AS] |

*Other agents for local oral treatment*

#### BENZYDAMINE

**Restricted benefit**

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1121B NP | ‡1 | 1 | .. | 21.70 | 23.10 | Difflam [IL] |

#### BENZYDAMINE

**Restricted benefit**

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5032W DP | ‡1 | .. | .. | 21.70 | 23.10 | Difflam [IL] |

## DRUGS FOR ACID RELATED DISORDERS

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

*H2-receptor antagonists*

#### FAMOTIDINE

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

**famotidine 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2487X NP | 1 | 5 | .. | 16.98 | 18.38 | Ausfam 20 [RW] |

**famotidine 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2488Y NP | 1 | 5 | .. | 16.98 | 18.38 | Ausfam 40 [RW] |

#### NIZATIDINE

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

**nizatidine 150 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1505F NP | 1 | 5 | .. | 23.43 | 24.83 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]7.59 | 31.02 | 24.83 | [a] Tazac [RW] | |

**nizatidine 300 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1504E NP | 1 | 5 | .. | 23.43 | 24.83 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]7.59 | 31.02 | 24.83 | [a] Tazac [RW] | |

## ▪ RANITIDINE

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

**ranitidine 150 mg/10 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8162N NP | 2 | 5 | .. | *30.23 | 30.00 | Zantac Syrup [AS] |

**ranitidine 150 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1978D NP MW | 1 | 5 | .. | 16.90 | 18.30 | APO-Ranitidine [TX] |

**ranitidine 300 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1977C NP | 1 | 5 | .. | 16.90 | 18.30 | APO-Ranitidine [TX] |

*Proton pump inhibitors*

## ▪ ESOMEPRAZOLE

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

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

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

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

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

**Authority required**

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**esomeprazole 40 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10330Q NP | 1 | 1 | .. | 20.29 | 21.69 | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8601Q NP | 1 | 1 | .. | 20.29 | 21.69 | [a] APO-Esomeprazole [TY]<br>[a] Esomeprazole GH [GQ]<br>[a] Esomeprazole Mylan [AL]<br>[a] Esopreze [BG]<br>[a] Nexole [RF] | [a] Esomeprazole Apotex [TX]<br>[a] Esomeprazole GxP [AF]<br>[a] Esomeprazole RBX [RA]<br>[a] Nexazole [RW]<br>[a] NOUMED ESOMEPRAZOLE [VO] |
| | | | [B]7.00 | 27.29 | 21.69 | [a] Nexium [AP] | |

## ▪ ESOMEPRAZOLE

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

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

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

**Note Continuing Therapy Only:**

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

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

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

**Authority required**

Scleroderma oesophagus

**Clinical criteria:**

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

**esomeprazole 40 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10331R NP | 1 | 5 | .. | 20.29 | 21.69 | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3401B | 1 | 5 | .. | 20.29 | 21.69 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |

| | | | | | |
|---|---|---|---|---|---|
| | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |
| | [B]7.00 | 27.29 | 21.69 | [a] Nexium [AP] | |

## ▪ ESOMEPRAZOLE

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

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

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

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

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

**Authority required (STREAMLINED)**

***8780***

Scleroderma oesophagus

**Authority required (STREAMLINED)**

***8827***

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**esomeprazole 20 mg enteric capsule, 30**

10343J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 17.29 | 18.69 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

8600P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |
| | | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |
| | [B]7.00 | 24.29 | 18.69 | [a] Nexium [AP] | | |

## ▪ ESOMEPRAZOLE

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

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

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

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

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

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

**Authority required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**esomeprazole 20 mg enteric capsule, 30**

11687D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 17.29 | 18.69 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

11692J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |
| | | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |
| | [B]7.00 | 24.29 | 18.69 | [a] Nexium [AP] | | |

## ▪ ESOMEPRAZOLE

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

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

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

**Authority required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**esomeprazole 20 mg enteric capsule, 30**

10295W (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 17.29 | 18.69 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

8886Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 17.29 | 18.69 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |
| | | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |
| | | [B]7.00 | 24.29 | 18.69 | [a] Nexium [AP] | |

## ▪ ESOMEPRAZOLE

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

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

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

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

**esomeprazole 20 mg enteric capsule, 30**

12275C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

12287Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |
| | | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |
| | | [B]14.00 | *35.59 | 22.99 | [a] Nexium [AP] | |

## ▪ ESOMEPRAZOLE

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

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

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

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

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

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

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

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

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

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

**esomeprazole 40 mg enteric capsule, 30**

12290W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *27.59 | 28.99 | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

12283L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *27.59 | 28.99 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole Apotex [TX] |
| | | | | | [a] Esomeprazole GH [GQ] | [a] Esomeprazole GxP [AF] |
| | | | | | [a] Esomeprazole Mylan [AL] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | [a] NOUMED ESOMEPRAZOLE [VO] |

| | | | | | |
|---|---|---|---|---|---|
| | [B]14.00 | *41.59 | 28.99 | [a] Nexium [AP] | |

## ▪ LANSOPRAZOLE

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

### lansoprazole 15 mg enteric capsule, 30

8198L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.90 | 18.30 | Zopral [AF] |

### lansoprazole 15 mg orally disintegrating tablet, 28

9331D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.82 | 18.22 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | [B]4.65 | 21.47 | 18.22 | [a] Zoton FasTabs [PF] | |

## ▪ LANSOPRAZOLE

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

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

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

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

**Authority required (STREAMLINED)**

***8780***

Scleroderma oesophagus

### lansoprazole 30 mg enteric capsule, 28

2241Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole [TX]<br>[a] NOUMED LANSOPRAZOLE [VO] | [a] Lanzopran [RA]<br>[a] Zopral [AF] |

### lansoprazole 30 mg orally disintegrating tablet, 28

9478W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | [B]5.23 | 23.04 | 19.21 | [a] Zoton FasTabs [PF] | |

## ▪ LANSOPRAZOLE

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

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

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

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

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

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

**Authority required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

### lansoprazole 30 mg enteric capsule, 28

11669E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole [TX]<br>[a] NOUMED LANSOPRAZOLE [VO] | [a] Lanzopran [RA]<br>[a] Zopral [AF] |

### lansoprazole 30 mg orally disintegrating tablet, 28

11697P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | [B]5.23 | 23.04 | 19.21 | [a] Zoton FasTabs [PF] | |

## ▪ LANSOPRAZOLE

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

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

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

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

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

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

**Authority required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**lansoprazole 30 mg enteric capsule, 28**

2240X (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole [TX]<br>[a] NOUMED LANSOPRAZOLE [VO] | [a] Lanzopran [RA]<br>[a] Zopral [AF] |

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

9477T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 17.81 | 19.21 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | [B]5.23 | 23.04 | 19.21 | [a] Zoton FasTabs [PF] | |

## ▪ LANSOPRAZOLE

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

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

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

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

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

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

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR

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

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

**lansoprazole 30 mg enteric capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12284M | 2 | 5 | .. | *22.63 | 24.03 | [a] APO-Lansoprazole [TX]<br>[a] NOUMED LANSOPRAZOLE [VO] | [a] Lanzopran [RA]<br>[a] Zopral [AF] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12276D | 2 | 5 | .. | *22.63 | 24.03 | [a] APO-Lansoprazole ODT [TX]<br>[a] Zopral ODT [AF] | [a] Lansoprazole ODT GH [GQ] |
| | | | [B]10.46 | *33.09 | 24.03 | [a] Zoton FasTabs [PF] | |

## ▪ OMEPRAZOLE

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**omeprazole 10 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8332M<br>NP | 1 | 5 | .. | 16.90 | 18.30 | Losec Tablets [PB] |

## ▪ OMEPRAZOLE

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

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

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

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

**Authority required (STREAMLINED)**

***8780***

Scleroderma oesophagus

**Authority required (STREAMLINED)**

***8866***

Zollinger-Ellison syndrome

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8333N<br>NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole generichealth [GQ] | [a] Maxor EC Tabs [AF]<br>[a] Ozmep [RW] |

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9110L<br>NP | 1 | 5 | .. | 17.29 | 18.69 | [a] Acimax Tablets [FJ]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [FQ] |
| | | | [B]7.15 | 24.44 | 18.69 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1327W<br>NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX]<br>[a] Pharmacor Omeprazole 20 [CR] | [a] Maxor [AF]<br>[a] Pemzo [RW]<br>[a] Probitor [SZ] |

## ▪ OMEPRAZOLE

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

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

**Authority required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11677N NP | 1 | 5 | .. | 17.29 | 18.69 | [a] Acimax Tablets [FJ]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [FQ] |
| | | | [B]7.15 | 24.44 | 18.69 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11683X NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole generichealth [GQ] | [a] Maxor EC Tabs [AF]<br>[a] Ozmep [RW] |

**omeprazole 20 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11682W NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX]<br>[a] Pharmacor Omeprazole 20 [CR] | [a] Maxor [AF]<br>[a] Pemzo [RW]<br>[a] Probitor [SZ] |

## ▪ OMEPRAZOLE

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

**Authority required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8331L NP | 1 | 1 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole generichealth [GQ] | [a] Maxor EC Tabs [AF]<br>[a] Ozmep [RW] |

**omeprazole 20 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9109K NP | 1 | 1 | .. | 17.29 | 18.69 | [a] Acimax Tablets [FJ]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [FQ] |
| | | | [B]7.15 | 24.44 | 18.69 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1326T NP | 1 | 1 | .. | 17.29 | 18.69 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX] | [a] Maxor [AF]<br>[a] Pemzo [RW] |

| | | |
|---|---|---|
| | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

## ▪ OMEPRAZOLE

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

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

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

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

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

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

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

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

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

**omeprazole 20 mg enteric tablet, 30**

12270T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] Acimax Tablets [FJ]<br>[a] Omeprazole Sandoz [SZ] | [a] Omepral [FQ] |
| | | [B]14.30 | *35.89 | 22.99 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

12272X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole generichealth [GQ] | [a] Maxor EC Tabs [AF]<br>[a] Ozmep [RW] |

**omeprazole 20 mg enteric capsule, 30**

12281J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Omeprazole [TX]<br>[a] Omeprazole Sandoz [HX]<br>[a] Pharmacor Omeprazole 20 [CR] | [a] Maxor [AF]<br>[a] Pemzo [RW]<br>[a] Probitor [SZ] |

## ▪ PANTOPRAZOLE

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**pantoprazole 20 mg enteric tablet, 30**

8399C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Pantoprazole [TX] | [a] NOUMED PANTOPRAZOLE [VO] |
| | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | [a] Pantoprazole APOTEX [TY] | [a] Pantoprazole generichealth [HQ] |
| | | | | | [a] Pantoprazole Sandoz [SZ] | [a] Salpraz [AF] |
| | | | | | [a] Somac [NQ] | [a] Sozol [RW] |

NP

## ▪ PANTOPRAZOLE

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

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

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

**Authority required (STREAMLINED)**

***8780***

Scleroderma oesophagus

**Authority required (STREAMLINED)**

***8866***

Zollinger-Ellison syndrome

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

9424B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 34.11 | 30.00 | Somac [NQ] |

NP

**pantoprazole 40 mg enteric tablet, 30**

8008L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.08 | 17.48 | [a] APO-Pantoprazole [TX] | [a] I-Pantoprazole [CR] |
| | | | | | [a] NOUMED PANTOPRAZOLE [VO] | [a] Ozpan [RA] |
| | | | | | [a] Panthron [ZS] | [a] Pantoprazole AN [EA] |
| | | | | | [a] Pantoprazole APOTEX [TY] | [a] Pantoprazole generichealth [HQ] |
| | | | | | [a] Pantoprazole Sandoz [SZ] | [a] Salpraz [AF] |
| | | | | | [a] Somac [NQ] | [a] Sozol [RW] |

NP

## ▪ PANTOPRAZOLE

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

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

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

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

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

**Authority required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

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

11678P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 34.11 | 30.00 | Somac [NQ] |

NP

**pantoprazole 40 mg enteric tablet, 30**

11681T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.08 | 17.48 | [a] APO-Pantoprazole [TX] | [a] I-Pantoprazole [CR] |
| | | | | | [a] NOUMED PANTOPRAZOLE [VO] | [a] Ozpan [RA] |
| | | | | | [a] Panthron [ZS] | [a] Pantoprazole AN [EA] |
| | | | | | [a] Pantoprazole APOTEX [TY] | [a] Pantoprazole generichealth [HQ] |
| | | | | | [a] Pantoprazole Sandoz [SZ] | [a] Salpraz [AF] |
| | | | | | [a] Somac [NQ] | [a] Sozol [RW] |

NP

## ▪ PANTOPRAZOLE

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

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

**Authority required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

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

9423Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 34.11 | 30.00 | Somac [NQ] |

**pantoprazole 40 mg enteric tablet, 30**

8007K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 16.08 | 17.48 | [a] APO-Pantoprazole [TX] | [a] I-Pantoprazole [CR] |
| | | | | | [a] NOUMED PANTOPRAZOLE [VO] | [a] Ozpan [RA] |
| | | | | | [a] Panthron [ZS] | [a] Pantoprazole AN [EA] |
| | | | | | [a] Pantoprazole APOTEX [TY] | [a] Pantoprazole generichealth [HQ] |
| | | | | | [a] Pantoprazole Sandoz [SZ] | [a] Salpraz [AF] |
| | | | | | [a] Somac [NQ] | [a] Sozol [RW] |

## ▪ PANTOPRAZOLE

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

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

- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

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

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

12282K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *55.23 | 30.00 | Somac [NQ] |

**pantoprazole 40 mg enteric tablet, 30**

12277E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *19.17 | 20.57 | [a] APO-Pantoprazole [TX] | [a] I-Pantoprazole [CR] |
| | | | | | [a] NOUMED PANTOPRAZOLE [VO] | [a] Ozpan [RA] |
| | | | | | [a] Panthron [ZS] | [a] Pantoprazole AN [EA] |
| | | | | | [a] Pantoprazole APOTEX [TY] | [a] Pantoprazole generichealth [HQ] |
| | | | | | [a] Pantoprazole Sandoz [SZ] | [a] Salpraz [AF] |
| | | | | | [a] Somac [NQ] | [a] Sozol [RW] |

## ▪ RABEPRAZOLE

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

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

8507R

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.73 | 18.13 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | [a] Rabeprazole Sandoz [SZ] | |
| | | [B]4.85 | 21.58 | 18.13 | [a] Pariet [JC] | |

## ▪ RABEPRAZOLE

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

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

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

**Authority required (STREAMLINED)**

***8780***

Scleroderma oesophagus

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

8508T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.57 | 17.97 | [a] APO-Rabeprazole [TX] | [a] Noumed Rabeprazole [VO] |
| | | | | | [a] Parbezol [RW] | [a] Rabeprazole Mylan [AF] |
| | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole SUN [RN] |
| | | | | | [a] Zabep [AL] | |
| | | [B]5.01 | 21.58 | 17.97 | [a] Pariet [JC] | |

## ▪ RABEPRAZOLE

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

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

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

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

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

**Authority required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

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

11670F

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.57 | 17.97 | [a] APO-Rabeprazole [TX] | [a] Noumed Rabeprazole [VO] |
| | | | | | [a] Parbezol [RW] | [a] Rabeprazole Mylan [AF] |
| | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole SUN [RN] |
| | | | | | [a] Zabep [AL] | |

| | | | | |
|---|---|---|---|---|
| [B]5.01 | 21.58 | 17.97 | [a] Pariet [JC] | |

## ▪ RABEPRAZOLE

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

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

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

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

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

**Authority required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8509W (NP) | 1 | 1 | .. | 16.57 | 17.97 | [a] APO-Rabeprazole [TX]<br>[a] Parbezol [RW]<br>[a] Rabeprazole Sandoz [SZ]<br>[a] Zabep [AL] | [a] Noumed Rabeprazole [VO]<br>[a] Rabeprazole Mylan [AF]<br>[a] Rabeprazole SUN [RN] |
| | | | [B]5.01 | 21.58 | 17.97 | [a] Pariet [JC] | |

## ▪ RABEPRAZOLE

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

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

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

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

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

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

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

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

**Treatment criteria:**

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

**Clinical criteria:**

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

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

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12286P | 2 | 5 | .. | *20.15 | 21.55 | [a] APO-Rabeprazole [TX]<br>[a] Parbezol [RW]<br>[a] Rabeprazole Sandoz [SZ]<br>[a] Zabep [AL] | [a] Noumed Rabeprazole [VO]<br>[a] Rabeprazole Mylan [AF]<br>[a] Rabeprazole SUN [RN] |
| | | | [B]10.02 | *30.17 | 21.55 | [a] Pariet [JC] | |

*Combinations for eradication of Helicobacter pylori*

## ▪ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN

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

**Restricted benefit**

Eradication of Helicobacter pylori

**Clinical criteria:**

- The condition must be associated with peptic ulcer disease.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10759G NP | ‡1 | .. | .. | 38.42 | 30.00 | [a] ESOMEPRAZOLE SANDOZ Hp7 [SZ] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8738X NP | ‡1 | .. | [B]4.96 | 43.38 | 30.00 | [a] Nexium Hp7 [AP] |

# ▪ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

## BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, tertiary amines*

## ▪ ATROPINE SULFATE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5022H DP | 1 | .. | .. | 24.66 | 26.06 | Pfizer Australia Pty Ltd [PF] |

## ▪ ATROPINE SULFATE

**Note Shared Care Model**:

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

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1089H NP | 1 | 1 | .. | 24.66 | 26.06 | Pfizer Australia Pty Ltd [PF] |

## PROPULSIVES

*Propulsives*

## ▪ DOMPERIDONE

**domperidone 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1347X NP | 1 | .. | .. | 15.25 | 16.65 | [a] APO-DOMPERIDONE [TX] | [a] Motilium [JT] |

## ▪ METOCLOPRAMIDE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1206L NP MW | 1 | .. | .. | 16.59 | 17.99 | Maxolon [IL] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5153F DP | 1 | .. | .. | 16.59 | 17.99 | Maxolon [IL] |

**metoclopramide hydrochloride 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1207M NP MW | 1 | .. | .. | 15.68 | 17.08 | [a] APO-Metoclopramide [TX]<br>[a] Pramin [AF] | [a] EMEXLON [RW] |
| | | | [B]3.55 | 19.23 | 17.08 | [a] Maxolon [IL] | |

**metoclopramide hydrochloride 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5151D DP | 1 | .. | .. | 15.68 | 17.08 | [a] APO-Metoclopramide [TX]<br>[a] Pramin [AF] | [a] EMEXLON [RW] |
| | | | [B]3.55 | 19.23 | 17.08 | [a] Maxolon [IL] | |

# ANTIEMETICS AND ANTINAUSEANTS

## ANTIEMETICS AND ANTINAUSEANTS

*Serotonin (5HT3) antagonists*

### GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**granisetron 3 mg/3 mL injection, 3 mL ampoule**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8729K NP | 1 | .. | .. | 15.90 | 17.30 | [a] Granisetron-AFT [AE]<br>[a] Kytril [IX] | [a] Granisetron Kabi [PK] |

### GRANISETRON

**Authority required (STREAMLINED)**

***4092***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**granisetron 3 mg/3 mL injection, 3 mL ampoule**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8730L NP | 1 | .. | .. | 15.90 | 17.30 | [a] Granisetron-AFT [AE]<br>[a] Kytril [IX] | [a] Granisetron Kabi [PK] |

### GRANISETRON

**Authority required (STREAMLINED)**

***10498***

Nausea and vomiting

**Clinical criteria:**

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

**granisetron 2 mg tablet, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8873B NP | 1 | 1 | .. | 57.56 | 30.00 | Kytril [IX] |

### GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**granisetron 2 mg tablet, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8728J NP | 2 | .. | .. | *30.81 | 30.00 | Kytril [IX] |

## ▪ NETUPITANT + PALONOSETRON

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

**Authority required (STREAMLINED)**
***5991***
Nausea and vomiting
**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**
***5994***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**
***6937***
Nausea and vomiting
**Clinical criteria:**

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

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**
***6879***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10731T NP | ‡1 | 5 | .. | 117.68 | 30.00 | Akynzeo [JZ] |

## ▪ ONDANSETRON

**Authority required (STREAMLINED)**
***10498***
Nausea and vomiting
**Clinical criteria:**

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

**ondansetron 4 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1594X NP | 1 | 1 | .. | 22.40 | 23.80 | [a] APO-Ondansetron [TX]<br>[a] Ondansetron AN [EA] | [a] APX-Ondansetron [TY]<br>[a] Ondansetron APOTEX [GX] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Ondansetron-DRLA [RZ] | [a] Ondansetron Mylan Tablets [AF] |
| | | | | | | [a] Ondansetron SZ [HX] | [a] Zofran [AS] |
| | | | | | | [a] Zotren 4 [RF] | |

**ondansetron 8 mg tablet, 10**

1595Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 24.63 | 26.03 | [a] APO-Ondansetron [TX] | [a] APX-Ondansetron [TY] |
| | | | | | [a] Ondansetron AN [EA] | [a] Ondansetron APOTEX [GX] |
| | | | | | [a] Ondansetron-DRLA [RZ] | [a] Ondansetron Mylan Tablets [AF] |
| | | | | | [a] Ondansetron SZ [HX] | [a] Zofran [AS] |
| | | | | | [a] Zotren 8 [RF] | |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

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

5470X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.90 | 18.30 | [a] APO-Ondansetron ODT [TX] | [a] APX-Ondansetron ODT [TY] |
| | | | | | [a] Ondansetron AN ODT [EA] | [a] Ondansetron Mylan ODT [AF] |
| | | | | | [a] Ondansetron ODT-DRLA [RZ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | [a] Zotren ODT [RF] | |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**ondansetron 4 mg tablet, 4**

8224W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.90 | 18.30 | [a] APO-Ondansetron [TX] | [a] APX-Ondansetron [TY] |
| | | | | | [a] Ondansetron AN [EA] | [a] Ondansetron APOTEX [GX] |
| | | | | | [a] Ondansetron-DRLA [RZ] | [a] Ondansetron Mylan Tablets [AF] |
| | | | | | [a] Ondansetron SZ [HX] | [a] Zofran [AS] |
| | | | | | [a] Zotren 4 [RF] | |

**ondansetron 8 mg tablet, 4**

8225X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.73 | 19.13 | [a] APO-Ondansetron [TX] | [a] APX-Ondansetron [TY] |
| | | | | | [a] Ondansetron AN [EA] | [a] Ondansetron APOTEX [GX] |
| | | | | | [a] Ondansetron-DRLA [RZ] | [a] Ondansetron Mylan Tablets [AF] |
| | | | | | [a] Ondansetron SZ [HX] | [a] Zofran [AS] |
| | | | | | [a] Zotren 8 [RF] | |

## ▪ ONDANSETRON

**Authority required (STREAMLINED)**

***4102***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

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

8233H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 99.84 | 30.00 | Zofran syrup 50 mL [AS] |

## ▪ ONDANSETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

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

9441X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 99.84 | 30.00 | Zofran syrup 50 mL [AS] |

## ▪ ONDANSETRON

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

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**ondansetron 8 mg wafer, 4**

8411Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | [B]2.44 | 21.19 | 20.15 | [a] Zofran Zydis [AS] |

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

5471Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.73 | 19.13 | [a] APO-Ondansetron ODT [TX] | [a] APX-Ondansetron ODT [TY] |
| | | | | | [a] Ondansetron AN ODT [EA] | [a] Ondansetron Mylan ODT [AF] |
| | | | | | [a] Ondansetron ODT-DRLA [RZ] | [a] Ondansetron SZ ODT [HX] |
| | | | | | [a] Zotren ODT [RF] | |

## ▪ ONDANSETRON

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

**Authority required (STREAMLINED)**

***10498***

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 4 mg orally disintegrating tablet, 10**

5472B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 22.40 | 23.80 | [a] APO-Ondansetron ODT [TX] | [a] APX-Ondansetron ODT [TY] |
| | | | | | [a] Ondansetron AN ODT [EA] | [a] Ondansetron Mylan ODT [AF] |
| | | | | | [a] Ondansetron ODT-DRLA [RZ] | [a] Ondansetron ODT Lupin [HQ] |
| | | | | | [a] Ondansetron SZ ODT [HX] | [a] Zotren ODT [RF] |

**ondansetron 4 mg wafer, 10**

8412R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | [B]2.46 | 24.86 | 23.80 | [a] Zofran Zydis [AS] |

## ▪ ONDANSETRON

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

**Authority required (STREAMLINED)**

***10498***

Nausea and vomiting

**Clinical criteria:**

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

**ondansetron 8 mg wafer, 10**

8413T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | [B]2.45 | 29.83 | 28.78 | [a] Zofran Zydis [AS] |

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

5473C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 24.63 | 26.03 | [a] APO-Ondansetron ODT [TX] | [a] APX-Ondansetron ODT [TY] |
| | | | | | [a] Ondansetron AN ODT [EA] | [a] Ondansetron Mylan ODT [AF] |
| | | | | | [a] Ondansetron ODT-DRLA [RZ] | [a] Ondansetron ODT Lupin [HQ] |
| | | | | | [a] Ondansetron SZ ODT [HX] | [a] Zotren ODT [RF] |

## ▪ PALONOSETRON

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

**Note** This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

5295Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 36.69 | 30.00 | [a] Aloxi [JZ] | [a] Palonosetron Dr.Reddy's [RZ] |

NP

## ▪ TROPISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

**tropisetron 5 mg/5 mL injection, 5 mL ampoule**

2746M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 17.97 | 19.37 | Tropisetron-AFT [AE] |

NP

*Other antiemetics*

## ▪ APREPITANT

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

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

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

**Authority required (STREAMLINED)**

***4211***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***4215***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6444***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)**

***6370***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**aprepitant 165 mg capsule, 1**

2518M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 79.97 | 30.00 | [a] Aprepitant APOTEX [TX] | [a] APREPITANT SCP [XC] |

## ▪ FOSAPREPITANT

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

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

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

**Authority required (STREAMLINED)**

***6886***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6891***

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

***6887***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**Authority required (STREAMLINED)**

***6852***

Nausea and vomiting

**Clinical criteria:**

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

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

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

**fosaprepitant 150 mg injection, 1 vial**

11107N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 87.43 | 30.00 | [a] Emend IV [MK] | [a] FOSAPREPITANT-AFT [AE] |

## ▪ PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5206B DP | 1 | .. | .. | 22.67 | 24.07 | Stemetil [SW] |

**prochlorperazine maleate 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5205Y DP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Prochlorperazine [TX] | [a] ProCalm [RW] |
| | | | | | | [a] Prochlorperazine GH [GQ] | [a] Stemzine [AV] |
| | | | [B]2.79 | 18.69 | 17.30 | [a] Stemetil [SW] | |

## ▪ PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**Note** As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2369Q NP | 1 | .. | .. | 22.67 | 24.07 | Stemetil [SW] |

**prochlorperazine maleate 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2893G NP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Prochlorperazine [TX] | [a] ProCalm [RW] |
| | | | | | | [a] Prochlorperazine GH [GQ] | [a] Stemzine [AV] |
| | | | [B]2.79 | 18.69 | 17.30 | [a] Stemetil [SW] | |

## ▪ PROMETHAZINE

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3374N DP | 2 | .. | .. | *31.33 | 30.00 | DBL Promethazine Hydrochloride [PF] |

# ▪ BILE AND LIVER THERAPY

## BILE THERAPY

*Bile acids and derivatives*

## ▪ OBETICHOLIC ACID

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

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

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Authority required (STREAMLINED)**

***12138***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

**Clinical criteria:**

- Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.

The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records.

**obeticholic acid 5 mg tablet, 30**

12630R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3793.13 | 30.00 | Ocaliva [EU] |

**obeticholic acid 10 mg tablet, 30**

12640G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3793.13 | 30.00 | Ocaliva [EU] |

## ▪ OBETICHOLIC ACID

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note** In accordance with the dosing directions in the approved Product Information, the 10 mg presentation is not PBS listed for initiation of treatment.

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

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

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

**Note** Special Pricing Arrangements apply.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Authority required**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

**Clinical criteria:**

- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.

**Population criteria:**

- Patient must be aged 18 years or older.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

**obeticholic acid 5 mg tablet, 30**

12623J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3793.13 | 30.00 | Ocaliva [EU] |

## ▪ OBETICHOLIC ACID

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

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

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

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

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

**Note** Special Pricing Arrangements apply.

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

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

**Authority required**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

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

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

**Clinical criteria:**

- Patient must have received treatment with this drug for this PBS indication prior to 1 September 2021, **AND**
- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have had, prior to initiating treatment with this drug, an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have had, prior to initiating treatment with this drug, a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have had, prior to initiating treatment with this drug, abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.

**Population criteria:**

- Patient must be aged 18 years or older.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

**obeticholic acid 5 mg tablet, 30**

12645M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3793.13 | 30.00 | Ocaliva [EU] |

**obeticholic acid 10 mg tablet, 30**

12631T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3793.13 | 30.00 | Ocaliva [EU] |

## ▪ URSODEOXYCHOLIC ACID

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***9032***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

**ursodeoxycholic acid 500 mg tablet, 100**

11180K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 295.88 | 30.00 | Ursofalk [FD] |

**ursodeoxycholic acid 250 mg capsule, 100**

8448P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | .. | *227.29 | 30.00 | [a] APO-Ursodeoxycholic acid [TX]<br>[a] Ursofalk [FD] | [a] Ursodox GH [GQ]<br>[a] Ursosan [BZ] |

# ▪ DRUGS FOR CONSTIPATION

## DRUGS FOR CONSTIPATION

*Contact laxatives*

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 5 mg enteric tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1259G NP | 1 | 2 | .. | 18.98 | 20.38 | Lax-Tab [AE] |

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1260H NP | 3 | 5 | .. | *25.62 | 27.02 | a | Petrus Bisacodyl Suppositories [PP] |
| | | | B1.29 | *26.91 | 27.02 | a | Dulcolax [VZ] |

**bisacodyl 10 mg suppository, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1258F NP | 3 | 4 | .. | *24.27 | 25.67 | Petrus Bisacodyl Suppositories [PP] |

*Bulk-forming laxatives*

## ▪ RHAMNUS FRANGULA + STERCULIA

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be receiving palliative care.

**Restricted benefit**
Terminal malignant neoplasia

**Restricted benefit**
Anorectal congenital abnormalities

**Restricted benefit**
Megacolon

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1104D NP | ‡1 | 1 | .. | 23.96 | 25.36 | Normacol Plus [NE] |

*Osmotically acting laxatives*

## ▪ MACROGOL-3350

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must have malignant neoplasia.

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**
Constipation
**Clinical criteria:**
- Patient must be receiving palliative care.

**Restricted benefit**
Chronic constipation
**Clinical criteria:**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**
Faecal impaction
**Clinical criteria:**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

3416T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP ‡1 | 5 | .. | 20.56 | 21.96 | OsmoLax [KY] |

## ▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 13.125 g/25 mL + sodium chloride 350.7 mg/25 mL + sodium bicarbonate 178.5 mg/25 mL + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL**

10126Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP 2 | 5 | .. | *23.07 | 24.47 | Movicol Liquid [NE] |

**macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets**

8612G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP ‡1 | 5 | .. | 20.56 | 21.96 | [a] APOHEALTH Macrogol with Electrolytes [GX]<br>[a] Chemists' Own Macrogol with Electrolytes [RW]<br>[a] Molaxole [GO] | [a] APO-MACROGOL plus ELECTROLYTES [TX]<br>[a] Macrovic [RF] |
| | | [B]2.12 | 22.68 | 21.96 | [a] Movicol [NE] | |

*Enemas*

## ▪ BISACODYL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1263L NP | ‡1 | 2 | .. | 31.76 | 30.00 | Bisalax [OX] |

## ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2091C NP | 2 | 2 | .. | *31.25 | 30.00 | Micolette [AE] |

# ▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

## INTESTINAL ANTIINFECTIVES

*Antibiotics*

## ▪ NYSTATIN

**nystatin 500 000 units capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1699K NP | 1 | .. | .. | 22.16 | 23.56 | Nilstat [AS] |

**nystatin 500 000 units capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3345C DP | 1 | .. | .. | 22.16 | 23.56 | Nilstat [AS] |

**nystatin 500 000 units tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1696G NP | 1 | .. | .. | 22.16 | 23.56 | Nilstat [AS] |

**nystatin 500 000 units tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3342X DP | 1 | .. | .. | 22.16 | 23.56 | Nilstat [AS] |

## ▪ RIFAXIMIN

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

**Authority required**

Prevention of hepatic encephalopathy

**Treatment criteria:**

- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

**Clinical criteria:**

- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

**rifaximin 550 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10001J | 1 | 5 | .. | 476.37 | 30.00 | Xifaxan [NE] |

## ▪ VANCOMYCIN

**Note** Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, **AND**
- The condition must be unresponsive to metronidazole.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**

- The condition must be due to **Clostridium difficile**, **AND**
- Patient must have an intolerance to metronidazole.

**vancomycin 125 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3113W | 2 | .. | .. | *157.49 | 30.00 | [a] Vancocin [AS] | [a] Vancomycin BNM 125mg [BZ] |

**vancomycin 250 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3114X | 2 | .. | .. | *306.93 | 30.00 | [a] Vancocin [AS] | [a] Vancomycin BNM 250mg [BZ] |

# ELECTROLYTES WITH CARBOHYDRATES

*Oral rehydration salt formulations*

## ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3196F | | | | | | |
| NP | ‡1 | .. | .. | 17.80 | 19.20 | O.R.S. [AF] |

## ▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

**Authority required**

Rehydration in intestinal failure

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11049M | 30 | .. | .. | *159.57 | 30.00 | O.R.S. [AF] |

# ANTIPROPULSIVES

*Antipropulsives*

## ▪ DIPHENOXYLATE + ATROPINE SULFATE

**diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2501P | | | | | | |
| NP | 1 | .. | .. | 15.90 | 17.30 | [a] Lofenoxal [IL] |
| | | | [B]3.33 | 19.23 | 17.30 | [a] Lomotil [IM] |

## ▪ LOPERAMIDE

**Authority required (STREAMLINED)**

***6364***

Diarrhoea

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**loperamide hydrochloride 2 mg capsule, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1571Q NP | 1 | .. | .. | 14.48 | 15.88 | [a] Gastrex [CR] | [a] Gastro-Stop [AS] |

## ▪ LOPERAMIDE

**Authority required**

Diarrhoea

**loperamide hydrochloride 2 mg capsule, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10889D NP | 5 | .. | .. | *20.42 | 21.82 | [a] Gastrex [CR] | [a] Gastro-Stop [AS] |

# INTESTINAL ANTIINFLAMMATORY AGENTS

*Corticosteroids acting locally*

## ▪ BUDESONIDE

**Note Continuing Therapy Only:**

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

**budesonide 2 mg/application enema, 2 x 14 applications**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10034D NP | 1 | 3 | .. | 151.45 | 30.00 | Budenofalk [FD] |

## ▪ BUDESONIDE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***12607***

Mild to moderate Crohn disease

**Clinical criteria:**

- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 12 weeks in any single course.

**budesonide 3 mg modified release capsule, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12915R NP | 1 | 2 | .. | 54.76 | 30.00 | Entocort [EU] |

## ▪ BUDESONIDE

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment - Induction of remission

**Clinical criteria:**

- Patient must have a history of symptoms of oesophageal dysfunction, **AND**
- Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per $mm^2$ hpf, **AND**
- Patient must not receive more than 90 days of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist.

Applications for treatment of this condition must be received within 12 weeks of biopsy.

Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation.

Diagnostic sensitivity increases with the number of biopsies and is optimised after taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

A histologic assessment of the oesophageal biopsy should be planned for approximately 8 weeks after the initiation of the first PBS-subsidised treatment with this drug under this restriction, and no later than 2 weeks prior to the patient completing

the PBS-subsidised initial treatment course, to determine the patient's eligibility for continuing therapy and to avoid an interruption to supply.

**budesonide 1 mg orally disintegrating tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12994X | 1 | 1 | .. | 617.63 | 30.00 | Jorveza [FD] |

## ▪ BUDESONIDE

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: First continuing treatment - Confirmation of remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have documented evidence of having achieved histologic remission while receiving initial PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per $mm^2$ hpf on oesophageal biopsy, **AND**
- Patient must not receive more than 26 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist.

Histologic assessment should be based on the peak eosinophils count derived from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by the same physician who confirmed the diagnosis of eosinophilic oesophagitis in the patient. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted and submitted after the patient has completed 8 weeks of the initial treatment course and no later than 2 weeks prior to the patient completing the PBS-subsidised initial treatment course, to avoid an interruption to supply. Where a histologic assessment is not undertaken and the results submitted, the patient will be not be eligible for ongoing treatment.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Subsequent continuing treatment - Maintenance of remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- The condition must not have progressed while being treated with this drug.

**Treatment criteria:**

- Must be treated by a gastroenterologist or in consultation with a gastroenterologist.

**budesonide 1 mg orally disintegrating tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12982G | 1 | 5 | .. | 414.41 | 30.00 | Jorveza [FD] |

**budesonide 500 microgram orally disintegrating tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12987M | 1 | 5 | .. | 414.41 | 30.00 | Jorveza [FD] |

## ▪ HYDROCORTISONE ACETATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**hydrocortisone acetate 10% enema, 21.1 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1502C NP | 2 | 3 | .. | *42.57 | 30.00 | Colifoam [GO] |

## ▪ PREDNISOLONE SODIUM PHOSPHATE

**Note Continuing Therapy Only:**

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

**prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL**

1920C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 3 | .. | *182.05 | 30.00 | Predsol [AS] |

## ▪ PREDNISOLONE SODIUM PHOSPHATE

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

**Restricted benefit**
Proctitis

**Restricted benefit**
Ulcerative colitis

**prednisolone (as sodium phosphate) 5 mg suppository, 10**

2554K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *40.29 | 30.00 | Predsol [AS] |

*Aminosalicylic acid and similar agents*

## ▪ BALSALAZIDE

**Note** Not for the treatment of Crohn disease

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

**Authority required (STREAMLINED)**
***7621***
Ulcerative colitis
**Clinical criteria:**
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 280**

11351K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 119.08 | 30.00 | Colazide [PK] |

## ▪ BALSALAZIDE

**Note** Not for the treatment of Crohn disease

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

**Authority required (STREAMLINED)**
***14306***
Ulcerative colitis
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 280**

13484Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *230.17 | 30.00 | Colazide [PK] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

**Restricted benefit**
Ulcerative colitis

**mesalazine 4 g modified release granules, 30 sachets**

10254Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 128.90 | 30.00 | Pentasa [FP] |

**mesalazine 3 g modified release granules, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10257W NP | 1 | 5 | .. | 101.19 | 30.00 | Salofalk [FD] |

**mesalazine 800 mg enteric tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11210B NP | 1 | 5 | .. | 78.64 | 30.00 | Asacol [EU] |

**mesalazine 1 g modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8599N NP | 1 | 5 | .. | 115.18 | 30.00 | Salofalk [FD] |

**mesalazine 1.6 g enteric tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12463Y NP | 2 | 4 | .. | *153.23 | 30.00 | Asacol [EU] |

**mesalazine 1.5 g modified release granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9206M NP | 1 | 5 | .. | 101.19 | 30.00 | Salofalk [FD] |

**mesalazine 500 mg modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8598M NP | 2 | 5 | .. | *122.65 | 30.00 | Salofalk [FD] |

## ▪ MESALAZINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Ulcerative colitis

**Restricted benefit**

Crohn disease

**mesalazine 1 g enteric tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11554D NP | 2 | 5 | .. | *137.29 | 30.00 | Salofalk [FD] |

**mesalazine 1 g modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12203G NP | 1 | 5 | .. | 106.50 | 30.00 | Pentasa [FP] |

**mesalazine 2 g modified release granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2287J NP | 1 | 5 | .. | 128.90 | 30.00 | Pentasa [FP] |

**mesalazine 1 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3413P NP | 2 | 5 | .. | *136.61 | 30.00 | Pentasa [FP] |

**mesalazine 250 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1611T NP | 1 | 5 | .. | 44.63 | 30.00 | Mesasal [GO] |

**mesalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8731M NP | 2 | 5 | .. | *122.65 | 30.00 | Salofalk [FD] |

**mesalazine 500 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2214M NP | 2 | 5 | .. | *122.65 | 30.00 | Pentasa [FP] |

## ▪ MESALAZINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

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

**Restricted benefit**

Crohn disease

**Clinical criteria:**

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

**mesalazine 1 g enteric tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13394Y NP | 4 | 5 | .. | *266.57 | 30.00 | Salofalk [FD] |

**mesalazine 1 g modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13355X NP | 2 | 5 | .. | *204.37 | 30.00 | Pentasa [FP] |

**mesalazine 2 g modified release granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13397D NP | 2 | 5 | .. | *249.81 | 30.00 | Pentasa [FP] |

**mesalazine 1 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13576M NP | 4 | 5 | .. | *265.25 | 30.00 | Pentasa [FP] |

**mesalazine 250 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13423L NP | 2 | 5 | .. | *76.27 | 30.00 | Mesasal [GO] |

**mesalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13362G NP | 4 | 5 | .. | *237.33 | 30.00 | Salofalk [FD] |

**mesalazine 500 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13396C NP | 4 | 5 | .. | *237.33 | 30.00 | Pentasa [FP] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

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

**mesalazine 4 g modified release granules, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13456F NP | 2 | 5 | .. | *249.81 | 30.00 | Pentasa [FP] |

**mesalazine 3 g modified release granules, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13518L NP | 2 | 5 | .. | *193.21 | 30.00 | Salofalk [FD] |

**mesalazine 800 mg enteric tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13422K NP | 2 | 5 | .. | *145.85 | 30.00 | Asacol [EU] |

**mesalazine 1 g modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13398E NP | 2 | 5 | .. | *222.37 | 30.00 | Salofalk [FD] |

**mesalazine 1.6 g enteric tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13395B NP | 4 | 4 | .. | *298.45 | 30.00 | Asacol [EU] |

**mesalazine 1.5 g modified release granules, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13460K NP | 2 | 5 | .. | *193.21 | 30.00 | Salofalk [FD] |

**mesalazine 500 mg modified release granules, 100 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13361F NP | 4 | 5 | .. | *237.33 | 30.00 | Salofalk [FD] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

Ulcerative colitis

**mesalazine 1.2 g modified release tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13247F NP | 1 | 5 | .. | 173.11 | 30.00 | [a] MESALZ [RA] |

**mesalazine 1.2 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9353G NP | 2 | 5 | .. | *173.11 | 30.00 | [a] Mesalazine 1.2 TAKEDA [NQ] | [a] Mezavant [TK] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

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

**mesalazine 1.2 g modified release tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13356Y NP | 2 | 5 | .. | *338.23 | 30.00 | [a] MESALZ [RA] |

**mesalazine 1.2 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13487W NP | 4 | 5 | .. | *338.25 | 30.00 | [a] Mesalazine 1.2 TAKEDA [NQ] | [a] Mezavant [TK] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

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

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

**Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

**mesalazine 1 g suppository, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5461K NP | 1 | 1 | .. | 99.36 | 30.00 | Salofalk [FD] |

**mesalazine 1 g suppository, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12198B NP | 1 | 1 | .. | 82.66 | 30.00 | Pentasa [FP] |

## ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

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

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

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4888***

Acute episode of mild to moderate ulcerative colitis

**mesalazine 1 g/100 mL enema, 7 x 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8753Q NP | 4 | 1 | .. | *214.81 | 30.00 | Pentasa [FP] |

**mesalazine 2 g/60 mL enema, 7 x 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8616L NP | 4 | 1 | .. | *214.81 | 30.00 | Salofalk [FD] |

**mesalazine 4 g/60 mL enema, 7 x 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8617M NP | 4 | 1 | .. | *331.53 | 30.00 | Salofalk [FD] |

**mesalazine 1 g/application enema, 14 applications**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8768L NP | 4 | 1 | .. | *247.33 | 30.00 | Salofalk [FD] |

## ▪ OLSALAZINE

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4824***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**olsalazine sodium 250 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1728Y NP | 1 | 5 | .. | 44.58 | 30.00 | Dipentum [IX] |

**olsalazine sodium 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8086N NP | 1 | 5 | .. | 68.63 | 30.00 | Dipentum [IX] |

## ▪ SULFASALAZINE

**Note Continuing Therapy Only:**

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

**sulfasalazine 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2093E NP | 2 | 5 | .. | *52.35 | 30.00 | Salazopyrin [PF] |

**sulfasalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2096H NP | 2 | 5 | .. | *56.33 | 30.00 | [a] Pyralin EN [FZ] |
| | | | [B]4.00 | *60.33 | 30.00 | [a] Salazopyrin-EN [PF] |

## ▪ SULFASALAZINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

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

**sulfasalazine 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13557M NP | 4 | 5 | .. | *91.73 | 30.00 | Salazopyrin [PF] |

**sulfasalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13433B NP | 4 | 5 | .. | *99.69 | 30.00 | [a] Pyralin EN [FZ] |
| | | | [B]8.00 | *107.69 | 30.00 | [a] Salazopyrin-EN [PF] |

# ▪ DIGESTIVES, INCL. ENZYMES

## DIGESTIVES, INCL. ENZYMES

*Enzyme preparations*

## ▪ PANCREATIC EXTRACT

**Note Continuing Therapy Only:**

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

**pancreatic extract 35 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12595X NP | 2 | 10 | .. | *161.37 | 30.00 | Creon 35,000 [GO] |

**pancreatic extract 10 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8020D NP | 5 | 10 | .. | *145.42 | 30.00 | Creon 10,000 [GO] |

**pancreatic extract 25 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8021E NP | 2 | 10 | .. | *117.57 | 30.00 | Creon 25,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5453B NP | 3 | 10 | .. | *112.95 | 30.00 | Creon Micro [GO] |

## ▪ PANCREATIC EXTRACT

**Note Continuing Therapy Only:**

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

**Restricted benefit**

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

**pancreatic extract 35 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13407P NP | 4 | 10 | .. | *314.77 | 30.00 | Creon 35,000 [GO] |

**pancreatic extract 10 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13560Q NP | 10 | 10 | .. | *282.87 | 30.00 | Creon 10,000 [GO] |

**pancreatic extract 25 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13470Y NP | 4 | 10 | .. | *227.13 | 30.00 | Creon 25,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13375Y NP | 6 | 10 | .. | *217.89 | 30.00 | Creon Micro [GO] |

## ▪ PANCRELIPASE

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

**Note** Pharmaceutical Benefits that have the brand Panzytrat 25 000 (Allergan) may be substituted for Pharmaceutical Benefits that have the brand Panzytrat 25 000 in the case of a shortage.

**pancrelipase 25 000 units capsule, 100**

12914Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 10 | .. | *213.97 | 30.00 | [a] Panzytrat 25 000 (Allergan) [DZ] |

**pancrelipase 25 000 units capsule, 100**

8366H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 10 | .. | *88.49 | 30.00 | [a] Panzytrat 25000 [TM] |

## ▪ PANCRELIPASE

**Note** Pharmaceutical Benefits that have the brand Panzytrat 25 000 (Allergan) may be substituted for Pharmaceutical Benefits that have the brand Panzytrat 25 000 in the case of a shortage.

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

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

**Restricted benefit**

Cystic fibrosis

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**pancrelipase 25 000 units capsule, 100**

12933Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 21 | .. | *213.97 | 30.00 | [a] Panzytrat 25 000 (Allergan) [DZ] |

**pancrelipase 25 000 units capsule, 100**

9229R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 21 | .. | *88.49 | 30.00 | [a] Panzytrat 25000 [TM] |

# ▪ DRUGS USED IN DIABETES

## INSULINS AND ANALOGUES

*Insulins and analogues for injection, fast-acting*

## ▪ INSULIN ASPART

**insulin aspart 100 units/mL injection, 5 x 3 mL pen devices**

12254Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | NovoRapid FlexPen [NF] |

**insulin aspart 100 units/mL injection, 1 x 10 mL vial**

8571D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 2 | .. | *100.77 | 30.00 | NovoRapid [NO] |

**insulin aspart 100 units/mL injection, 5 x 3 mL cartridges**

8435Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | NovoRapid Penfill 3 mL [NO] |

## ▪ INSULIN GLULISINE

**insulin glulisine 100 units/mL injection, 1 x 10 mL vial**

9224L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 2 | .. | *100.77 | 30.00 | Apidra [SW] |

**insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

1921D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.12 | 30.00 | Apidra [AV] |

**insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices**

12268Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.12 | 30.00 | Apidra SoloStar [SW] |

## ▪ INSULIN LISPRO

**insulin lispro 200 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11645X NP | 5 | 1 | .. | *266.42 | 30.00 | Humalog U200 Kwikpen [LY] |

**insulin lispro 100 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12237C NP | 5 | 1 | .. | *167.07 | 30.00 | Humalog KwikPen [KP] |

**insulin lispro 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8084L NP | 5 | 2 | .. | *100.77 | 30.00 | Humalog [LY] |

**insulin lispro 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8212F NP | 5 | 1 | .. | *167.07 | 30.00 | Humalog [LY] |

## ▪ INSULIN NEUTRAL HUMAN

**insulin neutral human 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1531N NP | 5 | 2 | .. | *86.07 | 30.00 | Actrapid [NO] | Humulin R [LY] |

**insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1762R NP | 5 | 1 | .. | *140.62 | 30.00 | Actrapid Penfill 3 mL [NO] | Humulin R [LY] |

*Insulins and analogues for injection, intermediate-acting*

## ▪ INSULIN ISOPHANE HUMAN

**insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12262J NP | 5 | 1 | .. | *140.62 | 30.00 | Protaphane InnoLet [NI] |

**insulin isophane human 100 units/mL injection, 1 x 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1533Q NP | 5 | 2 | .. | *86.07 | 30.00 | Humulin NPH [LY] | Protaphane [NO] |

**insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1761Q NP | 5 | 1 | .. | *140.62 | 30.00 | Humulin NPH [LY] | Protaphane Penfill 3 mL [NO] |

*Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting*

## ▪ INSULIN ASPART + INSULIN ASPART PROTAMINE

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12238D NP | 5 | 1 | .. | *167.07 | 30.00 | NovoMix 30 FlexPen [NF] |

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8609D NP | 5 | 1 | .. | *167.07 | 30.00 | NovoMix 30 Penfill 3 mL [NO] |

## ▪ INSULIN DEGLUDEC + INSULIN ASPART

**Note** Special Pricing Arrangements apply.

**insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11417X NP | 5 | 1 | .. | *380.52 | 30.00 | Ryzodeg Flextouch [NO] |

**insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11426J NP | 5 | 1 | .. | *380.52 | 30.00 | Ryzodeg Penfill [NO] |

## ▪ INSULIN LISPRO + INSULIN LISPRO PROTAMINE

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices**

12234X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | Humalog Mix25 KwikPen [KP] |

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices**

12261H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | Humalog Mix50 KwikPen [KP] |

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges**

8390N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | Humalog Mix25 [LY] |

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

8874C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *167.07 | 30.00 | Humalog Mix50 [LY] |

## ▪ INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL pen devices**

12255B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *140.62 | 30.00 | Mixtard 30/70 InnoLet [NI] |

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial**

1426C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 2 | .. | *86.07 | 30.00 | Humulin 30/70 [LY] |

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL cartridges**

1763T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5 | 1 | .. | *140.62 | 30.00 | Humulin 30/70 [LY] | Mixtard 30/70 Penfill 3 mL [NO] |

**insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges**

2062M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *147.07 | 30.00 | Mixtard 50/50 Penfill 3 mL [NO] |

*Insulins and analogues for injection, long-acting*

## ▪ INSULIN DETEMIR

**Note** Special Pricing Arrangements apply.

**Restricted benefit**
Type 1 diabetes

**insulin detemir 100 units/mL injection, 5 x 3 mL cartridges**

9040T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *355.77 | 30.00 | Levemir Penfill [NO] |

**insulin detemir 100 units/mL injection, 5 x 3 mL pen devices**

12236B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *355.77 | 30.00 | Levemir FlexPen [NF] |

## ▪ INSULIN GLARGINE

**insulin glargine 100 units/mL injection, 5 x 3 mL cartridges**

9039R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *186.97 | 30.00 | Optisulin [GZ] |

**insulin glargine 100 units/mL injection, 5 x 3 mL pen devices**

11815W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *186.97 | 30.00 | Optisulin SoloStar [WA] |

## ▪ INSULIN GLARGINE

**Note** Special Pricing Arrangements apply.

**insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices**

11308E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 1 | .. | *255.47 | 30.00 | Toujeo Solostar [SW] |

**insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11302W NP | 5 | 1 | .. | *420.37 | 30.00 | Toujeo Solostar [SW] |

## BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

*Biguanides*

### ▪ METFORMIN

**metformin hydrochloride 1 g tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8607B NP | 1 | 5 | .. | 17.76 | 19.16 | [a] APO-Metformin 1000 [TX] | [a] APX-Metformin [TY] |
| | | | | | | [a] Diaformin 1000 [AF] | [a] Formet 1000 [RW] |
| | | | | | | [a] Glucobete 1000 [ZS] | [a] Metformin AN [EA] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | [B]5.25 | 23.01 | 19.16 | [a] Diabex 1000 [AL] | |

**metformin hydrochloride 1 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3439B NP | 1 | 5 | .. | 17.41 | 18.81 | [a] APO-Metformin XR 1000 [TX] | [a] Blooms the Chemist Metformin XR 1000 [IB] |
| | | | | | | [a] Diaformin XR 1000 [AF] | [a] METEX XR [RF] |
| | | | | | | [a] Pharmacor Metformin XR [CR] | |
| | | | [B]5.25 | 22.66 | 18.81 | [a] Diabex XR 1000 [AL] | |

**metformin hydrochloride 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2430X NP | 1 | 5 | .. | 16.40 | 17.80 | [a] APO-Metformin 500 [TX] | [a] APX-Metformin [TY] |
| | | | | | | [a] Diaformin [AF] | [a] FORMET 500 [RF] |
| | | | | | | [a] Glucobete 500 [ZS] | [a] Metformin AN [EA] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | [B]5.29 | 21.69 | 17.80 | [a] Diabex [AL] | |

**metformin hydrochloride 500 mg modified release tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9435N NP | 1 | 5 | .. | 17.41 | 18.81 | [a] APO-Metformin XR 500 [TX] | [a] Blooms the Chemist Metformin XR 500 [IB] |
| | | | | | | [a] Metex XR [RW] | [a] Metformin XR 500 APOTEX [GX] |
| | | | | | | [a] Pharmacor Metformin XR [CR] | |
| | | | [B]5.25 | 22.66 | 18.81 | [a] Diabex XR 500 [AL] | |

**metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1801T NP | 1 | 5 | .. | 16.40 | 17.80 | [a] APO-Metformin 850 [TX] | [a] APX-Metformin [TY] |
| | | | | | | [a] Chem mart Metformin [CH] | [a] Diaformin 850 [AF] |
| | | | | | | [a] FORMET 850 [RF] | [a] Glucobete 850 [ZS] |
| | | | | | | [a] Metformin AN [EA] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] Terry White Chemists Metformin [TW] | |
| | | | [B]5.29 | 21.69 | 17.80 | [a] Diabex 850 [AL] | |

*Sulfonylureas*

### ▪ GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glibenclamide 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2939Q NP | 1 | 5 | .. | 16.90 | 18.30 | Daonil [SW] |

### ▪ GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**gliclazide 30 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8535F NP | 1 | 5 | .. | 19.02 | 20.42 | [a] APO-Gliclazide MR [TX] | [a] Glyade MR [AF] |
| | | | | | | [a] Pharmacor Gliclazide MR [CR] | |

**gliclazide 60 mg modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9302N NP | 1 | 5 | .. | 17.88 | 19.28 | [a] ARDIX GLICLAZIDE 60mg MR [XT] | [a] Gliclazide Lupin MR [GQ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Pharmacor Gliclazide MR [CR] | |
| | | | [B]7.63 | 25.51 | 19.28 | [a] Diamicron 60mg MR [SE] | |

**gliclazide 80 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2449X | | | | | | | |
| NP | 1 | 5 | .. | 18.85 | 20.25 | [a] APO-Gliclazide [TX] | [a] APX-Gliclazide [TY] |
| | | | | | | [a] Glyade [AF] | [a] Nidem [RW] |

## ▪ GLIMEPIRIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glimepiride 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8450R | | | | | | | |
| NP | 1 | 5 | .. | 15.90 | 17.30 | [a] Aylide 1 [AF] | [a] Glimepiride APOTEX [GX] |
| | | | | | | [a] Glimepiride Sandoz [SZ] | |
| | | | [B]2.08 | 17.98 | 17.30 | [a] Amaryl [SW] | |

**glimepiride 4 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8452W | | | | | | | |
| NP | 1 | 5 | .. | 16.60 | 18.00 | [a] Aylide 4 [AF] | [a] Glimepiride APOTEX [GX] |
| | | | | | | [a] Glimepiride Sandoz [SZ] | |
| | | | [B]2.03 | 18.63 | 18.00 | [a] Amaryl [SW] | |

**glimepiride 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8451T | | | | | | | |
| NP | 1 | 5 | .. | 15.90 | 17.30 | [a] Aylide 2 [AF] | [a] Glimepiride APOTEX [GX] |
| | | | | | | [a] Glimepiride Sandoz [SZ] | |
| | | | [B]2.03 | 17.93 | 17.30 | [a] Amaryl [SW] | |

**glimepiride 3 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8533D | | | | | | | |
| NP | 1 | 5 | .. | 16.09 | 17.49 | [a] Aylide 3 [AF] | [a] Glimepiride APOTEX [GX] |
| | | | | | | [a] Glimepiride Sandoz [SZ] | |
| | | | [B]2.03 | 18.12 | 17.49 | [a] Amaryl [SW] | |

## ▪ GLIPIZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glipizide 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2440K | | | | | | | |
| NP | 1 | 5 | .. | 21.06 | 22.46 | [a] Melizide [AF] | [a] Minidiab [PF] |

*Combinations of oral blood glucose lowering drugs*

## ▪ ALOGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4423***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***4427***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10035E NP | 1 | 5 | .. | 61.19 | 30.00 | Nesina Met 12.5/1000 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10033C NP | 1 | 5 | .. | 59.78 | 30.00 | Nesina Met 12.5/500 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10032B NP | 1 | 5 | .. | 60.78 | 30.00 | Nesina Met 12.5/850 [TK] |

## ▪ DAPAGLIFLOZIN + METFORMIN

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7498***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11300R | 1 | 5 | .. | 60.73 | 30.00 | Xigduo XR 5/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11313K | 1 | 5 | .. | 59.32 | 30.00 | Xigduo XR 10/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11270E | 1 | 5 | .. | 58.57 | 30.00 | Xigduo XR 10/500 [AP] |

## ▪ DAPAGLIFLOZIN + METFORMIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5631***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5739***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5798***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***5657***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***7492***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

10510E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 60.73 | 30.00 | Xigduo XR 5/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

10515K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.32 | 30.00 | Xigduo XR 10/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

10516L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.57 | 30.00 | Xigduo XR 10/500 [AP] |

## ▪ EMPAGLIFLOZIN + LINAGLIPTIN

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***7524***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

11269D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.54 | 30.00 | Glyxambi [BY] |

**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

11303X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.54 | 30.00 | Glyxambi [BY] |

## ▪ EMPAGLIFLOZIN + LINAGLIPTIN

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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

**Authority required (STREAMLINED)**

***7556***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11310G NP | 1 | 5 | .. | 82.54 | 30.00 | Glyxambi [BY] |

**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11298P NP | 1 | 5 | .. | 82.54 | 30.00 | Glyxambi [BY] |

## ▪ EMPAGLIFLOZIN + METFORMIN

**Authority required (STREAMLINED)**

***5953***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***7498***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10650M | 1 | 5 | .. | 62.62 | 30.00 | Jardiamet 5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10649L | 1 | 5 | .. | 64.14 | 30.00 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10639Y | 1 | 5 | .. | 62.62 | 30.00 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10640B | 1 | 5 | .. | 64.14 | 30.00 | Jardiamet 12.5 mg/1000 mg [BY] |

## ▪ EMPAGLIFLOZIN + METFORMIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***5966***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***5798***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***5657***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***7492***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10626G NP | 1 | 5 | .. | 62.62 | 30.00 | Jardiamet 5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10627H NP | 1 | 5 | .. | 64.14 | 30.00 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10633P NP | 1 | 5 | .. | 62.62 | 30.00 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10677Y NP | 1 | 5 | .. | 64.14 | 30.00 | Jardiamet 12.5 mg/1000 mg [BY] |

## ▪ LINAGLIPTIN + METFORMIN

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7507***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**

- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

11274J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 63.13 | 30.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

11294K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.20 | 30.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

11282T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.64 | 30.00 | Trajentamet [BY] |

## ▪ LINAGLIPTIN + METFORMIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6336***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***6443***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***7530***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

10038H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 63.13 | 30.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10045Q NP | 1 | 5 | .. | 64.20 | 30.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10044P NP | 1 | 5 | .. | 64.64 | 30.00 | Trajentamet [BY] |

## ▪ SAXAGLIPTIN + DAPAGLIFLOZIN

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***7524***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11286B | 1 | 5 | .. | 77.91 | 30.00 | Qtern 5/10 [AP] |

## ▪ SAXAGLIPTIN + DAPAGLIFLOZIN

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***7556***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11305B NP | 1 | 5 | .. | 77.91 | 30.00 | Qtern 5/10 [AP] |

## ▪ SAXAGLIPTIN + METFORMIN

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7507***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

11312J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.03 | 30.00 | Kombiglyze XR 5/500 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

11299Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.78 | 30.00 | Kombiglyze XR 5/1000 [AP] |

**saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

11285Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.19 | 30.00 | Kombiglyze XR 2.5/1000 [AP] |

## ▪ SAXAGLIPTIN + METFORMIN

**Note Continuing Therapy Only:**

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

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**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***6335***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***7530***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

10055F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.03 | 30.00 | Kombiglyze XR 5/500 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

10051B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.78 | 30.00 | Kombiglyze XR 5/1000 [AP] |

**saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

10048W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.19 | 30.00 | Kombiglyze XR 2.5/1000 [AP] |

## ▪ SITAGLIPTIN + METFORMIN

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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**Authority required (STREAMLINED)**

***7507***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR

- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

11566R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 44.69 | 30.00 | Janumet XR [XW] |

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

11574E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.75 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

11586T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 44.69 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

11582N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.44 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

11580L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 45.75 | 30.00 | Janumet XR [XW] |

## ▪ SITAGLIPTIN + METFORMIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6334***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***6443***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***7530***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

10089B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 44.69 | 30.00 | Janumet XR [XW] |

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

9451K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.75 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

9449H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 44.69 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

9450J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.44 | 30.00 | [a] Janumet [XW] | [a] Sitagliptin/Metformin Sandoz [SZ] |
| | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

10090C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 45.75 | 30.00 | Janumet XR [XW] |

## ▪ VILDAGLIPTIN + METFORMIN

**Note** This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6333***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

***6357***

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

**Authority required (STREAMLINED)**

***6344***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***6443***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5476F NP | 1 | 5 | .. | 57.60 | 30.00 | Galvumet 50/1000 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5474D NP | 1 | 5 | .. | 56.08 | 30.00 | Galvumet 50/500 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5475E NP | 1 | 5 | .. | 57.16 | 30.00 | Galvumet 50/850 [NV] |

*Alpha glucosidase inhibitors*

## ▪ ACARBOSE

**acarbose 100 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8189B NP | 1 | 5 | .. | 33.52 | 30.00 | [a] Acarbose Mylan [AF]<br>[a] GLYBOSAY [RW] | [a] Acarbose Viatris [AL] |

**acarbose 50 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8188Y NP | 1 | 5 | .. | 27.48 | 28.88 | [a] Acarbose Mylan [AF]<br>[a] GLYBOSAY [RW] | [a] Acarbose Viatris [AL] |

*Thiazolidinediones*

## ▪ PIOGLITAZONE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***4388***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***4364***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**pioglitazone 15 mg tablet, 28**

8694N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.63 | 21.03 | [a] Acpio 15 [RF]<br>[a] Actos [EW]<br>[a] Vexazone [AF] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX] |

**pioglitazone 30 mg tablet, 28**

8695P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 23.22 | 24.62 | [a] Acpio 30 [RF]<br>[a] Actos [EW]<br>[a] NOUMED PIOGLITAZONE [VO]<br>[a] Vexazone [AF] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX]<br>[a] Pioglitazone Sandoz [SZ] |

**pioglitazone 45 mg tablet, 28**

8696Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.29 | 27.69 | [a] Acpio 45 [RF]<br>[a] Actos [EW]<br>[a] NOUMED PIOGLITAZONE [VO]<br>[a] Vexazone [AF] | [a] Actaze [RW]<br>[a] APOTEX-Pioglitazone [TX]<br>[a] Pioglitazone Sandoz [SZ] |

*Dipeptidyl peptidase 4 (DPP-4) inhibitors*

## ▪ ALOGLIPTIN

**Note** Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***4349***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

**alogliptin 6.25 mg tablet, 28**

2944Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.28 | 30.00 | Nesina [TK] |

**alogliptin 12.5 mg tablet, 28**

2933J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.28 | 30.00 | Nesina [TK] |

**alogliptin 25 mg tablet, 28**

2986E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.28 | 30.00 | Nesina [TK] |

## ▪ LINAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7541***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**linagliptin 5 mg tablet, 30**

11280Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 59.08 | 30.00 | Trajenta [BY] |

## ▪ LINAGLIPTIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***6376***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***7505***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**linagliptin 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3387G NP | 1 | 5 | .. | 59.08 | 30.00 | Trajenta [BY] |

## ▪ SAXAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7541***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**saxagliptin 2.5 mg tablet, 28**

11292H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 56.01 | 30.00 | Onglyza [AP] |

**saxagliptin 5 mg tablet, 28**

11311H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 56.01 | 30.00 | Onglyza [AP] |

## ▪ SAXAGLIPTIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***7505***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**saxagliptin 2.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10128C NP | 1 | 5 | .. | 56.01 | 30.00 | Onglyza [AP] |

**saxagliptin 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8983T NP | 1 | 5 | .. | 56.01 | 30.00 | Onglyza [AP] |

## ▪ SITAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7541***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**sitagliptin 100 mg tablet, 28**

11576G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

**sitagliptin 25 mg tablet, 28**

11572C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

**sitagliptin 50 mg tablet, 28**

11573D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

## ▪ SITAGLIPTIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***6376***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***7505***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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**sitagliptin 100 mg tablet, 28**

9182G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

**sitagliptin 25 mg tablet, 28**

9180E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

**sitagliptin 50 mg tablet, 28**

9181F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.56 | 30.00 | [a] Januvia [XW] | [a] Sitagliptin Lupin [GQ] |
| | | | | | [a] Sitagliptin Sandoz Pharma [SZ] | [a] Sitagliptin SUN [RA] |
| | | | | | [a] Sitaglo [CR] | [a] Xelevia [XT] |

## ▪ VILDAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6346***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6363***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***6376***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**vildagliptin 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3415R NP | 1 | 5 | .. | 56.66 | 30.00 | Galvus [NV] |

*Glucagon-like peptide-1 (GLP-1) analogues*

## ▪ DULAGLUTIDE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7645***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5478***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR

- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5469***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

### dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

11364D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 133.80 | 30.00 | Trulicity [LY] |

## ▪ SEMAGLUTIDE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***5500***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5478***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***5469***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device**

12080T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 133.80 | 30.00 | Ozempic [NO] |

NP

**semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

12075M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 133.80 | 30.00 | Ozempic [NO] |

NP

*Sodium-glucose co-transporter 2 (SGLT2) inhibitors*

## ▪ DAPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***13230***

Chronic kidney disease

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 $m^2$ inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**dapagliflozin 10 mg tablet, 28**

13106T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 57.82 | 30.00 | Forxiga [AP] |

## ▪ DAPAGLIFLOZIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7528***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**dapagliflozin 10 mg tablet, 28**

11291G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 57.82 | 30.00 | Forxiga [AP] |

## ▪ DAPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

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

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

**Authority required (STREAMLINED)**

***12477***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

12823X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 57.82 | 30.00 | Forxiga [AP] |

## ▪ DAPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

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**Authority required (STREAMLINED)**

***7506***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***4991***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5629***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

***7495***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**dapagliflozin 10 mg tablet, 28**

10011X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 57.82 | 30.00 | Forxiga [AP] |

NP

## ▪ EMPAGLIFLOZIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

***7528***

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

11314L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.01 | 30.00 | Jardiance [BY] |

**empagliflozin 25 mg tablet, 30**

11281R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.01 | 30.00 | Jardiance [BY] |

## ▪ EMPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

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

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

**Authority required (STREAMLINED)**

***12477***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

12918X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.01 | 30.00 | Jardiance [BY] |

## ▪ EMPAGLIFLOZIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***7506***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***4991***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

***5629***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

***7495***

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**

- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

**Note** PBS-subsidised dual oral therapy does not include combination use of:a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**empagliflozin 10 mg tablet, 30**

10206E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.01 | 30.00 | Jardiance [BY] |

**empagliflozin 25 mg tablet, 30**

10202Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.01 | 30.00 | Jardiance [BY] |

# VITAMINS

## VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

*Vitamin D and analogues*

### CALCITRIOL

**Authority required (STREAMLINED)**

***5401***

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

***5255***

Hypoparathyroidism

**Authority required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

***5402***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

2502Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 29.11 | 30.00 | [a] APO-Calcitriol [TX] | [a] Calciprox [ZS] |
| | | | | | [a] Calcitriol AN [EA] | [a] CALITROL [ED] |
| | | | | | [a] Kosteo [RW] | [a] Sical [AF] |
| | | [B]2.29 | 31.40 | 30.00 | [a] Rocaltrol [IX] | |

### CALCITRIOL

**Authority required (STREAMLINED)**

***14322***

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

***14287***

Hypoparathyroidism

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***14231***

Hypophosphataemic rickets

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***14296***

Vitamin D-resistant rickets

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

***14259***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13457G NP | 2 | 3 | .. | *45.23 | 30.00 | [a] APO-Calcitriol [TX] | [a] Calciprox [ZS] |
| | | | | | | [a] Calcitriol AN [EA] | [a] CALITROL [ED] |
| | | | | | | [a] Kosteo [RW] | [a] Sical [AF] |
| | | | [B]4.58 | *49.81 | 30.00 | [a] Rocaltrol [IX] | |

## VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

*Vitamin B1, plain*

### ▪ THIAMINE

**Authority required (STREAMLINED)**

***5139***

Thiamine deficiency

**Clinical criteria:**

- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1070H NP | 1 | 2 | .. | 16.88 | 18.28 | Betavit [PP] |

### ▪ THIAMINE

**Authority required (STREAMLINED)**

***14319***

Thiamine deficiency

**Clinical criteria:**

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

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13354W NP | 2 | 2 | .. | *20.77 | 22.17 | Betavit [PP] |

# ▪ MINERAL SUPPLEMENTS

## CALCIUM

*Calcium*

## ▪ CALCIUM

**Authority required (STREAMLINED)**

***4586***

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11726E NP | 2 | 1 | .. | *29.07 | 30.00 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3117C NP | 1 | 1 | .. | 21.66 | 23.06 | Calci-Tab 600 [AE] |

## ▪ CALCIUM

**Authority required (STREAMLINED)**

***14228***

Hyperphosphataemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13485R NP | 4 | 1 | .. | *45.17 | 30.00 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13547B NP | 2 | 1 | .. | *30.33 | 30.00 | Calci-Tab 600 [AE] |

# POTASSIUM

*Potassium*

## ▪ POTASSIUM CHLORIDE

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1841X NP | 1 | 1 | .. | 24.82 | 26.22 | Span-K [AS] |

## ▪ POTASSIUM CHLORIDE

**Restricted benefit**

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

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13357B NP | 2 | 1 | .. | *36.65 | 30.00 | Span-K [AS] |

## ▪ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3012M NP | 1 | 1 | .. | 25.35 | 26.75 | Chlorvescent [AS] |

## ▪ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

**Restricted benefit**

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

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13486T NP | 2 | 1 | .. | *37.71 | 30.00 | Chlorvescent [AS] |

# OTHER MINERAL SUPPLEMENTS

*Magnesium*

## ▪ MAGNESIUM

**Authority required (STREAMLINED)**

***5506***

Hypomagnesaemia

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***5466***

Chronic renal disease

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**magnesium 37.4 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5146W NP | 1 | 5 | .. | 18.72 | 20.12 | MagMin (PBS) [BB] | Mag-Sup [PP] |

# ▪ OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

## OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

*Amino acids and derivatives*

## ▪ BETAINE

**Authority required**

Homocystinuria

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10119N | ‡1 | 5 | .. | 548.74 | 30.00 | Cystadane [RJ] |

*Various alimentary tract and metabolism products*

## ▪ SAPROPTERIN

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

**Authority required**

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11970B NP | 1 | 5 | .. | 4247.13 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

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

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

10087X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *5064.09 | 30.00 | Kuvan [IO] |

NP

## ▪ SAPROPTERIN

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must be untreated with this drug; OR
- Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; OR
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; OR
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11971C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4247.13 | 30.00 | Kuvan [IO] |

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

11676M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 875.31 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

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

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Authority required**

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11973E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4247.13 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

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

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

10086W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *5064.09 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.

Dietary phenylalanine intake must be maintained at a constant level.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11983Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4247.13 | 30.00 | Kuvan [IO] |

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

11691H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *5064.09 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

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

**Note** Request an appropriate maximum quantity based on testing response to treatment for 7 days, with the number of packs being a whole number, based on dosing no greater than 20 mg/kg per day. Combinations of the sachets and tablets are permitted to reduce high tablet burden.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Clinical criteria:**

- The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU), **AND**
- Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels.

**Treatment criteria:**

- Must be treated by a metabolic physician, **AND**
- Patient must be undergoing treatment with this drug for the first time, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be one of: (i) planning conception, (ii) pregnant.

**saproptерin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

12570N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4247.13 | 30.00 | Kuvan [IO] |

**saproptерin dihydrochloride 100 mg soluble tablet, 30**

12579C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 875.31 | 30.00 | Kuvan [IO] |

## ▪ SAPROPTERIN

**Note** Special Pricing Arrangements apply.

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

**Note** Request an appropriate maximum quantity (with the number of packs being a whole number) to provide approximately 30 days treatment duration per dispensing, based on dosing no greater than 20 mg/kg per day.

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Pre-conception through to when pregnancy first becomes known

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, following completion of this authority application, for more than 13 cumulative months (assuming 1 month consists of 30 days), **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be actively trying to conceive.

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

**Note** This PBS listing intends to subsidise up to 13 cumulative months (assuming 1 month consists of 30 days) of treatment during the pre-conception phase per known pregnancy. The time taken to conceive can vary for each patient, but where this treatment phase of 'pre-conception through to when pregnancy becomes first known' exceeds a cumulative 13 months, continued treatment beyond this time up to the point of conception, is not PBS subsidised.
13 cumulative months comprises of the time taken to achieve desired phenylalanine level control and the time taken for pregnancy to become known (e.g. If it takes 3 months to reach desired phenylalanine level control, 10 months of PBS-subsidised treatment remain in which to achieve pregnancy; if it takes only 1 month to reach desired phenylalanine level control, 12 months of PBS-subsidised treatment remain in which to achieve pregnancy)

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Existing pregnancy to birth

**Population criteria:**

- Patient must be pregnant.

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing further treatment with this drug as a PBS benefit, post-partum in the absence of actively trying to conceive a subsequent child/a known subsequent pregnancy, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Note** Request an appropriate number of repeats (whole number) relative to the expected birth date such that treatment is not continued post-partum by a whole prescription quantity. If the expected birth date is within the next 30 days at the time of the authority application, do not request repeats.

**Note** This PBS listing intends to subsidise treatment only whilst the patient is pregnant. Treatment is to be discontinued upon birth under this listing. Whilst a patient may benefit from continued treatment post-partum, continued treatment with this drug post-partum is not PBS subsidised in the absence of actively trying to conceive again/a known subsequent pregnancy.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12569M NP | 1 | 5 | .. | 875.31 | 30.00 | Kuvan [IO] |

## ▪ SODIUM PHENYLBUTYRATE

**Authority required (STREAMLINED)**

***9993***

Urea cycle disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m$^2$/day in patients weighing more than 20 kg.

**Authority required (STREAMLINED)**

***9919***

Urea cycle disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m$^2$/day in patients weighing more than 20 kg.

**sodium phenylbutyrate 483 mg/g granules, 174 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11865L NP | 3 | 5 | .. | *1639.86 | 30.00 | Pheburane [OH] |

## ▪ TRIENTINE

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

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

**Authority required**

Chelation of elevated copper levels

**Clinical criteria:**

- Patient must have a diagnosis of Wilson disease, **AND**
- Patient must be intolerant to penicillamine.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type: (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber; OR
- Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types; OR
- Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types.

Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of: (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels.

Document what these findings were in the patient's medical records. Do not supply them in this authority application.

Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine:

Side effects of penicillamine occurring soon after initiation (within first few weeks/months):

(i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.

Side effects of penicillamine developing later:

(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.

At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.

**trientine dihydrochloride 250 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13124R NP | 2 | 5 | .. | *2362.13 | 30.00 | Trientine Waymade [IX] |

# BLOOD AND BLOOD FORMING ORGANS

## ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

*Vitamin K antagonists*

### WARFARIN

**Caution** The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

**warfarin sodium 1 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2843P NP | 1 | 2 | .. | 17.75 | 19.15 | Coumadin [GO] | Marevan [GT] |

**warfarin sodium 2 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2209G NP | 1 | 2 | .. | 17.93 | 19.33 | Coumadin [GO] |

**warfarin sodium 3 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2844Q NP | 1 | 2 | .. | 17.99 | 19.39 | Marevan [GT] |

**warfarin sodium 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2211J NP | 1 | 2 | .. | 18.40 | 19.80 | Coumadin [GO] | Marevan [GT] |

*Heparin group*

### ENOXAPARIN SODIUM

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8510X NP | 2 | 1 | .. | *93.69 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8558K NP | 2 | 1 | .. | *85.21 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8262W NP | 1 | 1 | .. | 82.85 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8263X NP | 1 | 1 | .. | 87.26 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8264Y NP | 1 | 1 | .. | 111.48 | 30.00 | Clexane Safety-Lock [AV] |

### ENOXAPARIN SODIUM

**Restricted benefit**

Haemodialysis

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8639Q NP | 2 | 3 | .. | *93.69 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8716R NP | 2 | 3 | .. | *85.21 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8640R NP | 2 | 3 | .. | *154.69 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5434B NP | 2 | 3 | .. | *163.95 | 30.00 | Clexane Safety-Lock [AV] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5435C NP | 2 | 3 | .. | *214.81 | 30.00 | Clexane Safety-Lock [AV] |

## ▪ HEPARIN

**heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1466E NP | 1 | 5 | .. | 43.79 | 30.00 | DBL Heparin Sodium [PF] |

*Platelet aggregation inhibitors excl. heparin*

## ▪ ASPIRIN

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 100 mg tablet, 112**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8202Q NP | 1 | 1 | .. | 15.11 | 16.51 | Spren 100 [OW] |

## ▪ CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note Shared Care Model**:

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

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8358X NP | 1 | 5 | .. | 17.08 | 18.48 | [a] Clopidogrel Lupin [GQ] | [a] Clopidogrel Sandoz Pharma [HX] |
| | | | | | | [a] Clopidogrel Winthrop [WA] | [a] Iscover [AV] |
| | | | | | | [a] Piax [AF] | [a] Plavicor 75 [CR] |

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9354H NP | 1 | 5 | .. | 17.08 | 18.48 | [a] BTC Clopidogrel [JB] | [a] Clopidogrel GH [GQ] |
| | | | | | | [a] Clovix 75 [RW] | [a] Plidogrel [RF] |

## ▪ CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note Shared Care Model**:

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

**Restricted benefit**

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

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13365K NP | 2 | 5 | .. | *21.17 | 22.57 | [a] BTC Clopidogrel [JB] | [a] Clopidogrel GH [GQ] |
| | | | | | | [a] Clovix 75 [RW] | [a] Plidogrel [RF] |

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13399F NP | 2 | 5 | .. | *21.17 | 22.57 | [a] Clopidogrel Lupin [GQ] | [a] Clopidogrel Sandoz Pharma [HX] |
| | | | | | | [a] Clopidogrel Winthrop [WA] | [a] Iscover [AV] |
| | | | | | | [a] Piax [AF] | [a] Plavicor 75 [CR] |

## ▪ CLOPIDOGREL + ASPIRIN

**Note Shared Care Model**:

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

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9296G NP | 1 | 5 | .. | 17.37 | 18.77 | [a] APX-Clopidogrel/Aspirin 75/100 [TY]<br>[a] Clopidogrel Winthrop plus aspirin [WA]<br>[a] DuoPlidogrel [GZ] | [a] CLOPIDOGREL/ASPIRIN AN 75/100 [ED]<br>[a] DuoCover [AV]<br>[a] Piax Plus Aspirin [AF] |

## ▪ CLOPIDOGREL + ASPIRIN

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

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

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13427Q NP | 2 | 5 | .. | *21.75 | 23.15 | [a] APX-Clopidogrel/Aspirin 75/100 [TY]<br>[a] Clopidogrel Winthrop plus aspirin [WA]<br>[a] DuoPlidogrel [GZ] | [a] CLOPIDOGREL/ASPIRIN AN 75/100 [ED]<br>[a] DuoCover [AV]<br>[a] Piax Plus Aspirin [AF] |

## ▪ TICAGRELOR

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

**Authority required (STREAMLINED)**
***5746***
Acute coronary syndrome (myocardial infarction or unstable angina)
**Clinical criteria:**
- The treatment must be in combination with aspirin.

**ticagrelor 90 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1418P NP | 1 | 5 | .. | 130.81 | 30.00 | Brilinta [AP] |

## ▪ TICAGRELOR

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

**Authority required (STREAMLINED)**
***14240***
Acute coronary syndrome (myocardial infarction or unstable angina)
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with aspirin.

**ticagrelor 90 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13524T NP | 2 | 5 | .. | *253.63 | 30.00 | Brilinta [AP] |

## ▪ TIROFIBAN

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

**Authority required (STREAMLINED)**
***5782***
High risk of unstable angina
**Clinical criteria:**
- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

**Authority required (STREAMLINED)**

***5809***
High risk of unstable angina
**Clinical criteria:**
- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

**Authority required (STREAMLINED)**
***5691***
Non-Q-wave myocardial infarction

**tirofiban 12.5 mg/50 mL injection, 50 mL vial**

8350L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 183.08 | 30.00 | [a] Aggrastat [AS] | [a] Tirofiban Juno [JU] |

*Enzymes*

## ▪ TENECTEPLASE

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

**Restricted benefit**
Acute myocardial infarction
**Clinical criteria:**
- The treatment must be administrated within 12 hours of onset of attack.

**tenecteplase 40 mg injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack**

8526R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1874.70 | 30.00 | Metalyse [BY] |

## ▪ TENECTEPLASE

**Note** Pharmaceutical benefits that have the brand Metalyse 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack and pharmaceutical benefits that have the brand TNKase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack are equivalent for the purposes of substitution in the case of a shortage.

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

**Restricted benefit**
Acute myocardial infarction
**Clinical criteria:**
- The treatment must be administrated within 12 hours of onset of attack.

**tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

13128Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 5162.13 | 30.00 | [a] TNKase (Canada) [QY] | [a] TNKase (Canada) Medsurge Healthcare Pty Ltd [DZ] |

**tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

8527T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1970.77 | 30.00 | [a] Metalyse [BY] |

*Direct thrombin inhibitors*

## ▪ BIVALIRUDIN

**Authority required (STREAMLINED)**
***4919***
Coronary artery disease
**Treatment criteria:**
- Patient must be undergoing percutaneous coronary intervention.

**bivalirudin 250 mg injection, 1 vial**

8844L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 475.25 | 30.00 | Bivalirudin APOTEX [TX] |

## ▪ DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4402***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 110 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9321N NP | 1 | .. | .. | 82.53 | 30.00 | Pradaxa [BY] |

**dabigatran etexilate 75 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9320M NP | 1 | .. | .. | 101.82 | 30.00 | Pradaxa [BY] |

## ▪ DABIGATRAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4369***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9318K NP | 2 | 1 | .. | *42.61 | 30.00 | Pradaxa [BY] |

**dabigatran etexilate 110 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9319L NP | 2 | 1 | .. | *36.17 | 30.00 | Pradaxa [BY] |

## ▪ DABIGATRAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4381***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**dabigatran etexilate 75 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9322P NP | 2 | .. | .. | *42.61 | 30.00 | Pradaxa [BY] |

**dabigatran etexilate 110 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9323Q NP | 2 | .. | .. | *36.17 | 30.00 | Pradaxa [BY] |

## ▪ DABIGATRAN

**Note Shared Care Model**:

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

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

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 110 mg capsule, 60**

2753X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.53 | 30.00 | Pradaxa [BY] |

**dabigatran etexilate 150 mg capsule, 60**

2769R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.54 | 30.00 | Pradaxa [BY] |

## ▪ DABIGATRAN

**Note Shared Care Model**:

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

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

**Authority required (STREAMLINED)**

***14308***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 110 mg capsule, 60**

13523R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *154.03 | 30.00 | Pradaxa [BY] |

**dabigatran etexilate 150 mg capsule, 60**

13489Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *154.05 | 30.00 | Pradaxa [BY] |

*Direct factor Xa inhibitors*

## ▪ APIXABAN

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

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

**Authority required (STREAMLINED)**

***4402***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 60**

5061J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 90.73 | 30.00 | Eliquis [BQ] |

NP

## ▪ APIXABAN

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

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

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

**Authority required (STREAMLINED)**

***4098***

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***5098***

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 28**

10414D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 49.27 | 30.00 | Eliquis [BQ] |

NP

## ▪ APIXABAN

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

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

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

**Authority required (STREAMLINED)**

***4382***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**Authority required (STREAMLINED)**

***4409***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 15 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 30**

5054B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 51.86 | 30.00 | Eliquis [BQ] |

NP

## ▪ APIXABAN

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

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

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

**Authority required (STREAMLINED)**

***4381***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**Authority required (STREAMLINED)**

***4359***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 10 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 20**

5500L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 38.90 | 30.00 | Eliquis [BQ] |

NP

## ▪ APIXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

2744K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 90.73 | 30.00 | Eliquis [BQ] |

NP

## ▪ APIXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***14308***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

13464P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *171.25 | 30.00 | Eliquis [BQ] |

## ▪ APIXABAN

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

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

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

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***5083***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

2735Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 90.73 | 30.00 | Eliquis [BQ] |

## ▪ APIXABAN

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

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

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

**Authority required (STREAMLINED)**

***14308***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14264***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***14302***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

13525W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *171.25 | 30.00 | Eliquis [BQ] |

## ▪ RIVAROXABAN

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

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

**Authority required (STREAMLINED)**

***11013***

Chronic stable atherosclerotic disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy, **AND**
- Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; OR
- Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent, **AND**
- Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; OR
- Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%, **AND**
- The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication, **AND**
- Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of

fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

**rivaroxaban 2.5 mg tablet, 60**

12197Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 60.12 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**rivaroxaban 10 mg tablet, 30**

11633G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 66.36 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

**Note Shared Care Model**:

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

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

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

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

2691P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 62.22 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***4402***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9466F NP | 1 | 1 | .. | 39.68 | 30.00 | Xarelto [BN] |

**rivaroxaban 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9467G NP | 1 | .. | .. | 66.36 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***4382***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**rivaroxaban 10 mg tablet, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9469J NP | 1 | .. | .. | 39.68 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***14301***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13463N NP | 2 | 5 | .. | *111.45 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**rivaroxaban 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13521P NP | 2 | 5 | .. | *120.07 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

**Authority required (STREAMLINED)**

***10992***

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

**rivaroxaban 2.5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12192Q NP | 1 | 5 | .. | 60.12 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***4098***

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***4260***

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**rivaroxaban 15 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2160Q NP | 1 | .. | .. | 86.85 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

**Authority required (STREAMLINED)**

***14298***

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

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

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

**rivaroxaban 2.5 mg tablet, 60**

13366L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *107.25 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

***4268***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

2268J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.61 | 30.00 | Xarelto [BN] |

## ▪ RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

***14264***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

***14318***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

***14301***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13462M NP | 2 | 5 | .. | *110.23 | 30.00 | Xarelto [BN] |

*Other antithrombotic agents*

## ▪ FONDAPARINUX

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

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

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***5781***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED)**

***5808***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8775W NP | 3.5 | .. | .. | *117.40 | 30.00 | Arixtra [AS] |

# ▪ ANTIHEMORRHAGICS

## ANTIFIBRINOLYTICS

*Amino acids*

## ▪ TRANEXAMIC ACID

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**tranexamic acid 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2180R NP | 1 | 2 | .. | 38.62 | 30.00 | [a] APO-Tranexamic Acid [TX]<br>[a] Tranexamic Acid Lupin [GQ] | [a] Cyklokapron [PF] |

# ANTIANEMIC PREPARATIONS

## IRON PREPARATIONS

*Iron bivalent, oral preparations*

### FERROUS FUMARATE

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8985X NP | 1 | 1 | .. | 19.32 | 20.72 | Ferro-tab [AE] |

### FERROUS SULFATE

**ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8815Y NP | ‡1 | 2 | .. | 22.12 | 23.52 | Ferro-Liquid [AE] |

*Iron, parenteral preparations*

### FERRIC CARBOXYMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11702X NP | 1 | 1 | .. | 299.71 | 30.00 | Ferinject [VL] |

**iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10104T NP | 2 | 1 | .. | *299.73 | 30.00 | Ferinject [VL] |

### FERRIC DERISOMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric derisomaltose) 1 g/10 mL injection, 10 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12049E NP | 1 | 1 | .. | 299.71 | 30.00 | Monofer [PF] |

**iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11615H NP | 3 | .. | .. | *445.59 | 30.00 | Monofer [PF] |

### IRON POLYMALTOSE

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2593L NP | 1 | .. | .. | 33.42 | 30.00 | Ferrosig [SI] |

### IRON POLYMALTOSE

**Authority required (STREAMLINED)**

***4302***

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2805P NP | 1 | 5 | .. | 33.42 | 30.00 | Ferrosig [SI] |

## ▪ IRON SUCROSE

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

10229J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 39.06 | 30.00 | Venofer [VL] |

NP

## ▪ IRON SUCROSE

**Authority required (STREAMLINED)**

***4302***

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

8807M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 39.06 | 30.00 | Venofer [VL] |

NP

*Iron in combination with folic acid*

## ▪ FERROUS FUMARATE + FOLIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60**

9011G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 20.29 | 21.69 | Ferro-f-tab [AE] |

NP

## VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

## ▪ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin $B_{12}$ deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

2162T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.37 | 18.77 | [a] Cobal-B12 [JU] | [a] Vita-B12 [GH] |

NP

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

9048F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.37 | 18.77 | [a] Hydroxo-B12 [AS] | [a] Neo-B12 [PF] |

NP

*Folic acid and derivatives*

## ▪ FOLIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 500 microgram tablet, 100**

2958Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *17.19 | 18.59 | [a] Foltabs 500 [PP] | [a] Megafol 0.5 [AF] |

NP

## ▪ FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1437P NP | 2 | 1 | .. | *19.27 | 20.67 | Megafol 5 [AF] |

# ▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

## BLOOD AND RELATED PRODUCTS

*Blood substitutes and plasma protein fractions*

## ▪ HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9487H NP | 3 | .. | .. | *42.75 | 30.00 | Voluven 6% [PK] |

# ▪ OTHER HEMATOLOGICAL AGENTS

## OTHER HEMATOLOGICAL AGENTS

*Drugs used in hereditary angioedema*

## ▪ ICATIBANT

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

**Authority required**

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Increased maximum quantities will be limited to 12 injections per authority prescription.

**icatibant 30 mg/3 mL injection, 3 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1976B | 1 | 1 | .. | 851.63 | 30.00 | [a] Cipla Icatibant [LR]<br>[a] Icatibant Lupin [GQ] | [a] Fyzant [JU] |

## ▪ LANADELUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)

**Clinical criteria:**

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug, **AND**
- Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)

**Clinical criteria:**

- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Continuing preventative treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate.

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be aged 12 years or older.

Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

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

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### lanadelumab 300 mg/2 mL injection, 2 mL syringe

12790E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 18602.23 | 30.00 | Takhzyro [TK] |

# CARDIOVASCULAR SYSTEM

## CARDIAC THERAPY

### CARDIAC GLYCOSIDES

*Digitalis glycosides*

#### DIGOXIN

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

**digoxin 50 microgram/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3164M NP | 2 | 3 | .. | *43.19 | 30.00 | Lanoxin [AS] |

**digoxin 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1322N NP | 1 | 1 | .. | 16.90 | 18.30 | [a] Sigmaxin [LN] |
| | | | [B]2.41 | 19.31 | 18.30 | [a] Lanoxin [AS] |

**digoxin 62.5 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2605D NP | 1 | 1 | .. | 16.90 | 18.30 | [a] Sigmaxin-PG [LN] |
| | | | [B]2.41 | 19.31 | 18.30 | [a] Lanoxin-PG [AS] |

### ANTIARRHYTHMICS, CLASS I AND III

*Antiarrhythmics, class Ia*

#### DISOPYRAMIDE

**Note** Pharmaceutical benefits that have the form disopyramide 100 mg capsule in a pack size of 84 can be substituted for a pack size of 100 in the case of a shortage.

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

**disopyramide 100 mg capsule, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13280Y NP | 1.19 | 5 | .. | *86.73 | 30.00 | [a] Rythmodan (Canada) [OJ] |

**disopyramide 100 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2923W NP | 1 | 5 | .. | 25.46 | 26.86 | [a] Rythmodan [PB] |

*Antiarrhythmics, class Ib*

#### LIDOCAINE

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

**lidocaine hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2876J NP | 1 | .. | .. | 35.09 | 30.00 | Xylocard 500 [AS] |

*Antiarrhythmics, class Ic*

#### FLECAINIDE

**Caution** Flecainide acetate should be avoided in patients with poor cardiac function.

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

**Restricted benefit**
Serious supra-ventricular cardiac arrhythmias

**Restricted benefit**
Serious ventricular cardiac arrhythmias

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**flecainide acetate 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1090J NP | 1 | 5 | .. | 37.17 | 30.00 | [a] APO-Flecainide [TX]<br>[a] Flecatab [AF] | [a] Flecainide Sandoz [SZ] |
| | | | [B]3.19 | 40.36 | 30.00 | [a] Tambocor [IL] | |

**flecainide acetate 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1088G NP | 1 | 5 | .. | 32.49 | 30.00 | [a] APO-Flecainide [TX]<br>[a] Flecatab [AF] | [a] Flecainide Sandoz [SZ] |
| | | | [B]3.19 | 35.68 | 30.00 | [a] Tambocor [IL] | |

*Antiarrhythmics, class III*

## ▪ AMIODARONE

**Note** This drug has been reported to cause frequent and potentially serious toxicity.

**Note** Regular monitoring of hepatic and thyroid function is recommended.

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

**Restricted benefit**
Severe cardiac arrhythmias

**amiodarone hydrochloride 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2344J NP | 1 | 5 | .. | 17.40 | 18.80 | [a] Aratac 100 [AF] | [a] Cordarone X 100 [SW] |

**amiodarone hydrochloride 200 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2343H NP | 1 | 5 | .. | 19.42 | 20.82 | [a] Amdarone [XT]<br>[a] APO-Amiodarone [TX]<br>[a] Cordarone X 200 [SW] | [a] Amiodarone Sandoz [SZ]<br>[a] Aratac 200 [AF] |

## ▪ SOTALOL

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

**Restricted benefit**
Severe cardiac arrhythmias

**sotalol hydrochloride 160 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2043M NP | 1 | 5 | .. | 19.90 | 21.30 | [a] APO-Sotalol [TX]<br>[a] Cardol [AF]<br>[a] Sotalol Sandoz [SZ] | [a] APX-Sotalol [TY]<br>[a] Solavert [RF] |
| | | | [B]4.99 | 24.89 | 21.30 | [a] Sotacor [RW] | |

**sotalol hydrochloride 80 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8398B NP | 1 | 5 | .. | 16.89 | 18.29 | [a] APO-Sotalol [TX]<br>[a] Cardol [AF]<br>[a] Sotalol Sandoz [SZ] | [a] APX-Sotalol [TY]<br>[a] Solavert [RF] |
| | | | [B]4.58 | 21.47 | 18.29 | [a] Sotacor [RW] | |

## CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

*Adrenergic and dopaminergic agents*

## ▪ ADRENALINE (EPINEPHRINE)

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1016L NP | 1 | 1 | .. | 20.63 | 22.03 | Link Medical Products Pty Ltd [LM] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5004J DP | 1 | .. | .. | 20.63 | 22.03 | Link Medical Products Pty Ltd [LM] |

## ▪ ADRENALINE (EPINEPHRINE)

**Caution** Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

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

**Note** No applications for repeats will be authorised.

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

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12655C NP | 2 | .. | .. | *159.69 | 30.00 | Anapen 500 [XT] |

**adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8697R NP | 2 | .. | .. | *159.69 | 30.00 | [a] Adrenaline Jr Viatris [AF]<br>[a] EpiPen Jr. [AL] | [a] Anapen Junior 150 [XT] |

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8698T NP | 2 | .. | .. | *159.69 | 30.00 | [a] Adrenaline Viatris [AF]<br>[a] EpiPen [AL] | [a] Anapen 300 [XT] |

## VASODILATORS USED IN CARDIAC DISEASES

*Organic nitrates*

## ▪ GLYCERYL TRINITRATE

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1516T NP | 1 | 5 | .. | 34.26 | 30.00 | Transiderm-Nitro 50 [SZ] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8028M NP | 1 | 5 | .. | 34.26 | 30.00 | Minitran 10 [IL] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1515R NP | 1 | 5 | .. | 29.21 | 30.00 | Transiderm-Nitro 25 [SZ] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8027L NP | 1 | 5 | .. | 29.21 | 30.00 | Minitran 5 [IL] |

**glyceryl trinitrate 15 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8119H NP | 1 | 5 | .. | 37.14 | 30.00 | Minitran 15 [IL] |

## ▪ GLYCERYL TRINITRATE

**Note** The spray should not be inhaled.

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8171C NP | ‡1 | 5 | .. | 24.91 | 26.31 | Nitrolingual Pumpspray [SW] |

## ▪ GLYCERYL TRINITRATE

**Restricted benefit**

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

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13580R NP | 2 | 5 | .. | *55.53 | 30.00 | Transiderm-Nitro 50 [SZ] |

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13490B NP | 2 | 5 | .. | *45.43 | 30.00 | Transiderm-Nitro 25 [SZ] |

## ▪ GLYCERYL TRINITRATE

**Note** The spray should not be inhaled.

**Restricted benefit**

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

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13549D NP | ‡2 | 5 | .. | *36.83 | 30.00 | Nitrolingual Pumpspray [SW] |

## ▪ ISOSORBIDE DINITRATE

**isosorbide dinitrate 5 mg sublingual tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2588F NP | 2 | 2 | .. | *20.51 | 21.91 | Isordil Sublingual [RW] |

## ▪ ISOSORBIDE DINITRATE

**Restricted benefit**

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

**isosorbide dinitrate 5 mg sublingual tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13491C NP | 4 | 2 | .. | *28.05 | 29.45 | Isordil Sublingual [RW] |

## ▪ ISOSORBIDE MONONITRATE

**isosorbide mononitrate 60 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1558B NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Isosorbide Mononitrate [TX] | [a] Duride [AF] |
| | | | | | | [a] ISOBIDE MR [RF] | [a] Isosorbide AN [EA] |
| | | | [B]2.49 | 19.24 | 18.15 | [a] Monodur 60 mg [IY] | |
| | | | [B]3.38 | 20.13 | 18.15 | [a] Imdur Durule [IX] | |

**isosorbide mononitrate 120 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8273K NP | 1 | 5 | .. | 20.31 | 21.71 | [a] Monodur 120 mg [IY] |
| | | | [B]3.37 | 23.68 | 21.71 | [a] Imdur 120 mg [IX] |

## ▪ ISOSORBIDE MONONITRATE

**Restricted benefit**

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

**isosorbide mononitrate 60 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13461L NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Isosorbide Mononitrate [TX] | [a] Duride [AF] |
| | | | | | | [a] ISOBIDE MR [RF] | [a] Isosorbide AN [EA] |
| | | | [B]4.98 | *25.49 | 21.91 | [a] Monodur 60 mg [IY] | |
| | | | [B]6.76 | *27.27 | 21.91 | [a] Imdur Durule [IX] | |

**isosorbide mononitrate 120 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13611J NP | 2 | 5 | .. | *27.63 | 29.03 | [a] Monodur 120 mg [IY] |
| | | | [B]6.74 | *34.37 | 29.03 | [a] Imdur 120 mg [IX] |

*Other vasodilators used in cardiac diseases*

## ▪ NICORANDIL

**Note Shared Care Model**:

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

**nicorandil 10 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8228C NP | ‡1 | 5 | .. | 23.22 | 24.62 | [a] APO-Nicorandil [TX] | [a] Ikorel [SW] |
| | | | | | | [a] Ikotab [AF] | |

**nicorandil 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8229D NP | ‡1 | 5 | .. | 27.24 | 28.64 | [a] APO-Nicorandil [TX] | [a] Ikorel [SW] |
| | | | | | | [a] Ikotab [AF] | |

## ▪ NICORANDIL

**Note Shared Care Model**:

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

**Restricted benefit**

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

**nicorandil 10 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13550E NP | ‡2 | 5 | .. | *33.45 | 30.00 | [a] APO-Nicorandil [TX] | [a] Ikorel [SW] |
| | | | | | | [a] Ikotab [AF] | |

**nicorandil 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13551F NP | ‡2 | 5 | .. | *41.49 | 30.00 | [a] APO-Nicorandil [TX] | [a] Ikorel [SW] |
| | | | | | | [a] Ikotab [AF] | |

## ▪ PERHEXILINE

**Note** Regular monitoring of drug serum levels is recommended.

**Note Shared Care Model**:

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

**Authority required (STREAMLINED)**

***5592***

Angina

**Clinical criteria:**

- The condition must not be responding to other therapy.

**perhexiline maleate 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1822X NP | 1 | 5 | .. | 54.48 | 30.00 | Pexsig [AS] |

## ▪ VERICIGUAT

**Note** Special Pricing Arrangements apply.

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

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

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

**Authority required (STREAMLINED)**

***13561***

Chronic heart failure

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**vericiguat 10 mg tablet, 28**

13192H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

**vericiguat 2.5 mg tablet, 28**

13178N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

**vericiguat 5 mg tablet, 28**

13189E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

## ▪ VERICIGUAT

**Note** Special Pricing Arrangements apply.

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

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

**Note** The date of the decompensation event and date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated.

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

**Authority required**

Chronic heart failure

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist.

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%, **AND**
- The condition must be stabilised following a decompensation event that required at least one of: (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months, **AND**
- Patient must not have clinical signs of fluid overload, **AND**
- Patient must not have received intravenous treatment for fluid overload in the previous 24 hours, **AND**
- Patient must not have a systolic blood pressure less than 100 mmHg, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**Authority required**

Chronic heart failure

Treatment Phase: Grandfather treatment

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist.

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022,

**AND**

- Patient must have been symptomatic with NYHA classes II, III or IV prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a documented left ventricular ejection fraction (LVEF) of less than 45% prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have been, at the time of initiating non-PBS-subsidised treatment with this drug, stabilised following a decompensation event that required at least one of: (i) hospitalisation in the 6 months prior to initiating non-PBS-subsidised drug for this PBS indication, (ii) intravenous diuretic therapy in the three months prior to initiating non-PBS-subsidised drug for this PBS indication, **AND**
- Patient must not have had clinical signs of fluid overload at the time of initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received intravenous treatment in the 24 hours prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have a systolic blood pressure less than 100 mmHg, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

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

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

**vericiguat 10 mg tablet, 28**

13193J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

**vericiguat 2.5 mg tablet, 28**

13181R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

**vericiguat 5 mg tablet, 28**

13186B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 143.91 | 30.00 | Verquvo [BN] |

## OTHER CARDIAC PREPARATIONS

*Other cardiac preparations*

### ▪ IVABRADINE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4979***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10012Y NP | 1 | 5 | .. | 46.35 | 30.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |

**ivabradine 7.5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2960T NP | 1 | 5 | .. | 46.35 | 30.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |

# ANTIHYPERTENSIVES

## ANTIADRENERGIC AGENTS, CENTRALLY ACTING

*Methyldopa*

### METHYLDOPA

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

**Authority required**

Hypertension

**Population criteria:**

- Patient must be pregnant.

**methyldopa 250 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1629R NP | 1 | 5 | .. | 21.79 | 23.19 | Aldomet [AS] |

*Imidazoline receptor agonists*

### CLONIDINE

**clonidine hydrochloride 100 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3145M NP | 1 | 5 | .. | 25.32 | 26.72 | [a] APO-Clonidine [TX]<br>[a] Clonidine Lupin [GQ] | [a] Catapres 100 [IX] |

**clonidine hydrochloride 150 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3141H NP | 1 | 5 | .. | 31.49 | 30.00 | Catapres [IX] |

### CLONIDINE

**Restricted benefit**

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

**clonidine hydrochloride 100 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13578P NP | 2 | 5 | .. | *37.65 | 30.00 | [a] APO-Clonidine [TX]<br>[a] Clonidine Lupin [GQ] | [a] Catapres 100 [IX] |

**clonidine hydrochloride 150 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13548C NP | 2 | 5 | .. | *49.99 | 30.00 | Catapres [IX] |

### GUANFACINE

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***9034***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

**Authority required (STREAMLINED)**

***9031***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Authority required (STREAMLINED)**

***8544***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

**Authority required (STREAMLINED)**

***8585***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

**guanfacine 4 mg modified release tablet, 28**

11441E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 126.25 | 30.00 | Intuniv [TK] |

**guanfacine 1 mg modified release tablet, 28**

11452R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 126.25 | 30.00 | Intuniv [TK] |

**guanfacine 2 mg modified release tablet, 28**

11451Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 126.25 | 30.00 | Intuniv [TK] |

**guanfacine 3 mg modified release tablet, 28**

11440D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 126.25 | 30.00 | Intuniv [TK] |

## ▪ MOXONIDINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

9019Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.43 | 19.83 | [a] APO-Moxonidine [TX]<br>[a] Moxonidine GX [SZ] | [a] Moxonidine GH [GQ]<br>[a] Moxonidine MYL [AF] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Moxonidine Viatris [AL]<br>[a] Physiotens [GO] | [a] Moxotens [RF] |

**moxonidine 400 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9020R<br>NP | 1 | 5 | .. | 22.26 | 23.66 | [a] APO-Moxonidine [TX]<br>[a] Moxonidine GX [SZ]<br>[a] Moxonidine Viatris [AL]<br>[a] Physiotens [GO] | [a] Moxonidine GH [GQ]<br>[a] Moxonidine MYL [AF]<br>[a] Moxotens [RF] |

## ▪ MOXONIDINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13579Q<br>NP | 2 | 5 | .. | *23.87 | 25.27 | [a] APO-Moxonidine [TX]<br>[a] Moxonidine GX [SZ]<br>[a] Moxonidine Viatris [AL]<br>[a] Physiotens [GO] | [a] Moxonidine GH [GQ]<br>[a] Moxonidine MYL [AF]<br>[a] Moxotens [RF] |

**moxonidine 400 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13552G<br>NP | 2 | 5 | .. | *31.53 | 30.00 | [a] APO-Moxonidine [TX]<br>[a] Moxonidine GX [SZ]<br>[a] Moxonidine Viatris [AL]<br>[a] Physiotens [GO] | [a] Moxonidine GH [GQ]<br>[a] Moxonidine MYL [AF]<br>[a] Moxotens [RF] |

## ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

*Alpha-adrenoreceptor antagonists*

## ▪ PRAZOSIN

**prazosin 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1479W<br>NP | 1 | 5 | .. | 17.12 | 18.52 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1480X<br>NP | 1 | 5 | .. | 18.87 | 20.27 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1478T<br>NP | 1 | 5 | .. | 23.55 | 24.95 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

## ▪ PRAZOSIN

**Restricted benefit**

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

**prazosin 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13553H<br>NP | 2 | 5 | .. | *21.25 | 22.65 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13400G<br>NP | 2 | 5 | .. | *24.75 | 26.15 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13367M<br>NP | 2 | 5 | .. | *34.11 | 30.00 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

*Hydrazinophthalazine derivatives*

## ▪ HYDRALAZINE

**hydralazine hydrochloride 25 mg tablet, 100**

1640H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *20.67 | 22.07 | Alphapress 25 [AF] |

NP

**hydralazine hydrochloride 50 mg tablet, 100**

1639G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *21.91 | 23.31 | Alphapress 50 [AF] |

NP

*Pyrimidine derivatives*

## ▪ MINOXIDIL

**Note** Pharmaceutical benefits that have the form minoxidil 10 mg tablet in a pack size of 60 can be substituted for a pack size of 100 in the case of a shortage.

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

**Restricted benefit**

Severe refractory hypertension

**Clinical criteria:**

- The treatment must be initiated by a consultant physician.

**minoxidil 10 mg tablet, 60**

13279X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1.67 | 5 | .. | *125.62 | 30.00 | [a] Minoxidil 10 mg (Roma Pharmaceuticals) [OJ] |

NP

**minoxidil 10 mg tablet, 100**

2313R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 43.91 | 30.00 | [a] Loniten [PF] |

NP

# ▪ DIURETICS

## LOW-CEILING DIURETICS, THIAZIDES

*Thiazides, plain*

## ▪ HYDROCHLOROTHIAZIDE

**hydrochlorothiazide 25 mg tablet, 100**

1484D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 21.14 | 22.54 | Dithiazide [FF] |

NP

## ▪ HYDROCHLOROTHIAZIDE

**Restricted benefit**

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

**hydrochlorothiazide 25 mg tablet, 100**

13409R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *29.29 | 30.00 | Dithiazide [FF] |

NP

## LOW-CEILING DIURETICS, EXCL. THIAZIDES

*Sulfonamides, plain*

## ▪ CHLORTALIDONE

**chlortalidone 25 mg tablet, 50**

1585K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *20.87 | 22.27 | Hygroton 25 [GH] |

NP

## ▪ CHLORTALIDONE

**Restricted benefit**

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

**chlortalidone 25 mg tablet, 50**

13500M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 1 | .. | *28.77 | 30.00 | Hygroton 25 [GH] |

NP

## ▪ INDAPAMIDE

### indapamide hemihydrate 1.5 mg modified release tablet, 90

8532C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 20.70 | 22.10 | [a] APO-Indapamide SR [TX]<br>[a] Tenaxil SR [RW] | [a] Odaplix SR [AF] |
| | | [B]7.15 | 27.85 | 22.10 | [a] Natrilix SR [SE] | |

### indapamide hemihydrate 2.5 mg tablet, 90

2436F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 18.27 | 19.67 | [a] Dapa-Tabs [AF] | [a] Insig [RW] |

## ▪ INDAPAMIDE

**Restricted benefit**

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

### indapamide hemihydrate 1.5 mg modified release tablet, 90

13475F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 1 | .. | *28.41 | 29.81 | [a] APO-Indapamide SR [TX]<br>[a] Tenaxil SR [RW] | [a] Odaplix SR [AF] |
| | | [B]14.30 | *42.71 | 29.81 | [a] Natrilix SR [SE] | |

### indapamide hemihydrate 2.5 mg tablet, 90

13378D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 1 | .. | *23.55 | 24.95 | [a] Dapa-Tabs [AF] | [a] Insig [RW] |

# HIGH-CEILING DIURETICS

*Sulfonamides, plain*

## ▪ FUROSEMIDE

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

2413B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 16.11 | 17.51 | Lasix [SW] |

### furosemide 10 mg/mL oral liquid, 30 mL

2411X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 29.01 | 30.00 | Lasix [SW] |

### furosemide 40 mg tablet, 100

2412Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 15.70 | 17.10 | Urex [RW]<br>[a] APO-Frusemide [TX]<br>[a] FUROSEMIDE AN [EA]<br>[a] Uremide [AF] | [a] Frusax [ZS]<br>[a] NOUMED FUROSEMIDE [VO] |
| | | [B]1.04 | 16.74 | 17.10 | [a] Frusemix [TY] | |

### furosemide 500 mg tablet, 50

2415D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 22.80 | 24.20 | Urex-Forte [RW] |

## ▪ FUROSEMIDE

**Restricted benefit**

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

### furosemide 10 mg/mL oral liquid, 30 mL

13504R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 3 | .. | *45.03 | 30.00 | Lasix [SW] |

### furosemide 40 mg tablet, 100

13472C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 1 | .. | *18.41 | 19.81 | Urex [RW]<br>[a] APO-Frusemide [TX]<br>[a] FUROSEMIDE AN [EA]<br>[a] Uremide [AF] | [a] Frusax [ZS]<br>[a] NOUMED FUROSEMIDE [VO] |
| | | [B]2.08 | *20.49 | 19.81 | [a] Frusemix [TY] | |

**furosemide 500 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13474E NP | 2 | 3 | .. | *32.61 | 30.00 | Urex-Forte [RW] |

## ▪ FUROSEMIDE

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

**furosemide 20 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1810G NP | 2 | 1 | .. | *18.37 | 19.77 | [a] Frusemix-M [TY] | [a] Urex-M [RW] |

**furosemide 20 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2414C NP | 1 | 1 | .. | 18.37 | 19.77 | [a] APO-Frusemide [TX] | [a] FUROSEMIDE AN [EA] |
| | | | [B]1.06 | 19.43 | 19.77 | [a] Frusemix-M [TY] | |

## ▪ FUROSEMIDE

**Note** Pharmaceutical benefits that have the form furosemide 20 mg tablet, 50 and pharmaceutical benefits that have the form furosemide 20 mg tablet, 100 are equivalent for the purposes of substitution.

**Restricted benefit**

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

**furosemide 20 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13501N NP | 4 | 1 | .. | *23.77 | 25.17 | [a] Frusemix-M [TY] | [a] Urex-M [RW] |

**furosemide 20 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13473D NP | 2 | 1 | .. | *23.75 | 25.15 | [a] APO-Frusemide [TX] | [a] FUROSEMIDE AN [EA] |
| | | | [B]2.12 | *25.87 | 25.15 | [a] Frusemix-M [TY] | |

# ALDOSTERONE ANTAGONISTS AND OTHER POTASSIUM-SPARING AGENTS

*Aldosterone antagonists*

## ▪ EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***4937***

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**eplerenone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8879H NP | 1 | 5 | .. | 53.62 | 30.00 | [a] APO-Eplerenone [TX]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [UJ] |

**eplerenone 50 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8880J NP | 1 | 5 | .. | 53.62 | 30.00 | [a] APO-Eplerenone [TX]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [UJ] |

## ▪ EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***14266***

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**eplerenone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13590G NP | 2 | 5 | .. | *94.25 | 30.00 | [a] APO-Eplerenone [TX]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [UJ] |

**eplerenone 50 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13379E NP | 2 | 5 | .. | *94.25 | 30.00 | [a] APO-Eplerenone [TX]<br>[a] Inpler [AF] | [a] ESPLER [RW]<br>[a] Inspra [UJ] |

## ▪ FINERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14097***

Chronic kidney disease with Type 2 diabetes

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 $m^2$ or greater, prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug, **AND**
- The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant, **AND**
- Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic, **AND**
- Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.

**finerenone 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13335W NP | 1 | 5 | .. | 84.04 | 30.00 | Kerendia [BN] |

**finerenone 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13316W NP | 1 | 5 | .. | 84.04 | 30.00 | Kerendia [BN] |

## ▪ SPIRONOLACTONE

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2340E NP | 1 | 5 | .. | 27.80 | 29.20 | [a] Spironolactone Viatris 100 [AL] |
| | | | [B]4.50 | 32.30 | 29.20 | [a] Spiractin 100 [AF] |
| | | | [B]7.50 | 35.30 | 29.20 | [a] Aldactone [PF] |

**spironolactone 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2339D NP | 1 | 5 | .. | 16.75 | 18.15 | [a] Spironolactone Viatris 25 [AL] |
| | | | [B]4.65 | 21.40 | 18.15 | [a] Spiractin 25 [AF] |

| | | | | | |
|---|---|---|---|---|---|
| | | [B]7.65 | 24.40 | 18.15 | [a] Aldactone [PF] |

## ▪ SPIRONOLACTONE

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**Restricted benefit**

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

**spironolactone 25 mg tablet, 100**

13503Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] Spironolactone Viatris 25 [AL] |
| | | [B]9.30 | *29.81 | 21.91 | [a] Spiractin 25 [AF] |
| | | [B]15.30 | *35.81 | 21.91 | [a] Aldactone [PF] |

# DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

*Low-ceiling diuretics and potassium-sparing agents*

## ▪ AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

1486F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *23.13 | 24.53 | Moduretic [AS] |

## ▪ AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

**Restricted benefit**

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

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

13410T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 1 | .. | *33.29 | 30.00 | Moduretic [AS] |

# OTHER DIURETICS

*Vasopressin antagonists*

## ▪ TOLVAPTAN

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Note** Special Pricing Arrangements apply.

**Authority required**

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 $m^2$ at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition.

Rapidly progressing disease is defined as either of the following:

A decline in eGFR of greater than or equal to 5 mL/min/1.73 $m^2$ within one year;

OR

An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 $m^2$ per year over a five year period.

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

11602P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

11597J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

11588X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12460T | 1 | 5 | .. | 946.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12461W | 1 | 5 | .. | 946.84 | 30.00 | Jinarc [OS] |

## ▪ TOLVAPTAN

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***8288***

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m$^2$, **AND**
- Patient must not have had a kidney transplant.

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11600M | 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11593E | 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11596H | 1 | 5 | .. | 1828.84 | 30.00 | Jinarc [OS] |

**tolvaptan 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12457P | 1 | 5 | .. | 946.84 | 30.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12462X | 1 | 5 | .. | 946.84 | 30.00 | Jinarc [OS] |

# ▪ PERIPHERAL VASODILATORS

## PERIPHERAL VASODILATORS

*Other peripheral vasodilators*

## ▪ PHENOXYBENZAMINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1862B NP | 1 | 5 | .. | 752.30 | 30.00 | Dibenyline [GH] |

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1166J NP | 3 | 5 | .. | *677.88 | 30.00 | Amdipharm Mercury (Australia) Pty Limited [GH] |

# BETA BLOCKING AGENTS

## BETA BLOCKING AGENTS

*Beta blocking agents, non-selective*

### OXPRENOLOL

**oxprenolol hydrochloride 40 mg tablet, 100**

2961W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 36.57 | 30.00 | Corbeton 40 [AF] |

### PROPRANOLOL

**propranolol hydrochloride 10 mg tablet, 100**

2565B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.28 | 17.68 | [a] APO-Propranolol [TX] |
| | | [B]2.99 | 19.27 | 17.68 | [a] Deralin 10 [AF] |
| | | [B]8.48 | 24.76 | 17.68 | [a] Inderal [IX] |

**propranolol hydrochloride 40 mg tablet, 100**

2566C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.55 | 17.95 | [a] APO-Propranolol [TX] |
| | | [B]2.99 | 19.54 | 17.95 | [a] Deralin 40 [AF] |
| | | [B]8.48 | 25.03 | 17.95 | [a] Inderal [IX] |

### PROPRANOLOL

**Restricted benefit**

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

**propranolol hydrochloride 10 mg tablet, 100**

13386M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *19.57 | 20.97 | [a] APO-Propranolol [TX] |
| | | [B]5.98 | *25.55 | 20.97 | [a] Deralin 10 [AF] |
| | | [B]16.96 | *36.53 | 20.97 | [a] Inderal [IX] |

**propranolol hydrochloride 40 mg tablet, 100**

13542R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *20.11 | 21.51 | [a] APO-Propranolol [TX] |
| | | [B]5.98 | *26.09 | 21.51 | [a] Deralin 40 [AF] |
| | | [B]16.96 | *37.07 | 21.51 | [a] Inderal [IX] |

*Beta blocking agents, selective*

### ATENOLOL

**atenolol 50 mg tablet, 30**

1081X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Atenolol [TX]<br>[a] Atenolol Amneal [EF]<br>[a] Atenolol Sandoz [SZ]<br>[a] Tensig [RW] | [a] APX-Atenolol [TY]<br>[a] Atenolol GH [GQ]<br>[a] Noten [AF] |
| | | [B]13.44 | 29.14 | 17.10 | [a] Tenormin [IX] | |

### ATENOLOL

**Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

2243C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 46.31 | 30.00 | Atenolol-AFT [AE] |

### ATENOLOL

**Restricted benefit**

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

**atenolol 50 mg tablet, 30**

13540P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Atenolol [TX]<br>[a] Atenolol Amneal [EF]<br>[a] Atenolol Sandoz [SZ]<br>[a] Tensig [RW] | [a] APX-Atenolol [TY]<br>[a] Atenolol GH [GQ]<br>[a] Noten [AF] |

| | | | | | |
|---|---|---|---|---|---|
| [B]26.88 | *45.29 | 19.81 | [a] Tenormin [IX] | | |

## ▪ ATENOLOL

**Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

**Clinical criteria:**

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

### atenolol 50 mg/10 mL oral liquid, 300 mL

13600T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | .. | *79.63 | 30.00 | Atenolol-AFT [AE] |

NP

## ▪ BISOPROLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### bisoprolol fumarate 10 mg tablet, 28

8606Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.22 | 22.62 | [a] APO-Bisoprolol [TX] | [a] Bicard 10 [RW] |
| | | | | | [a] Bisoprolol Dr.Reddy's [RI] | [a] Bisoprolol generichealth [GQ] |
| | | | | | [a] Bisoprolol Sandoz [SZ] | [a] Bispro 10 [AF] |
| | | | | | [a] Cipla Bisoprolol [LR] | [a] NOUMED BISOPROLOL [VO] |
| | | [B]6.70 | 27.92 | 22.62 | [a] Bicor [AL] | |

### bisoprolol fumarate 2.5 mg tablet, 28

8604W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.26 | 19.66 | [a] APO-Bisoprolol [TX] | [a] Bicard 2.5 [RW] |
| | | | | | [a] Bisoprolol Dr.Reddy's [RI] | [a] Bisoprolol generichealth [GQ] |
| | | | | | [a] Bisoprolol Sandoz [SZ] | [a] Bispro 2.5 [AF] |
| | | | | | [a] Cipla Bisoprolol [LR] | [a] NOUMED BISOPROLOL [VO] |
| | | [B]6.74 | 25.00 | 19.66 | [a] Bicor [AL] | |

### bisoprolol fumarate 5 mg tablet, 28

8605X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.57 | 20.97 | [a] APO-Bisoprolol [TX] | [a] Bicard 5 [RW] |
| | | | | | [a] Bisoprolol Dr.Reddy's [RI] | [a] Bisoprolol generichealth [GQ] |
| | | | | | [a] Bisoprolol Sandoz [SZ] | [a] Bispro 5 [AF] |
| | | | | | [a] Cipla Bisoprolol [LR] | [a] NOUMED BISOPROLOL [VO] |
| | | [B]6.70 | 26.27 | 20.97 | [a] Bicor [AL] | |

## ▪ BISOPROLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### bisoprolol fumarate 10 mg tablet, 28

13444N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *29.45 | 30.00 | [a] APO-Bisoprolol [TX] | [a] Bicard 10 [RW] |
| | | | | | [a] Bisoprolol Dr.Reddy's [RI] | [a] Bisoprolol generichealth [GQ] |
| | | | | | [a] Bisoprolol Sandoz [SZ] | [a] Bispro 10 [AF] |
| | | | | | [a] Cipla Bisoprolol [LR] | [a] NOUMED BISOPROLOL [VO] |
| | | [B]13.40 | *42.85 | 30.00 | [a] Bicor [AL] | |

**bisoprolol fumarate 2.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13419G NP | 2 | 5 | .. | *23.53 | 24.93 | [a] APO-Bisoprolol [TX]<br>[a] Bisoprolol Dr.Reddy's [RI]<br>[a] Bisoprolol Sandoz [SZ]<br>[a] Cipla Bisoprolol [LR] | [a] Bicard 2.5 [RW]<br>[a] Bisoprolol generichealth [GQ]<br>[a] Bispro 2.5 [AF]<br>[a] NOUMED BISOPROLOL [VO] |
| | | | [B]13.48 | *37.01 | 24.93 | [a] Bicor [AL] | |

**bisoprolol fumarate 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13443M NP | 2 | 5 | .. | *26.15 | 27.55 | [a] APO-Bisoprolol [TX]<br>[a] Bisoprolol Dr.Reddy's [RI]<br>[a] Bisoprolol Sandoz [SZ]<br>[a] Cipla Bisoprolol [LR] | [a] Bicard 5 [RW]<br>[a] Bisoprolol generichealth [GQ]<br>[a] Bispro 5 [AF]<br>[a] NOUMED BISOPROLOL [VO] |
| | | | [B]13.40 | *39.55 | 27.55 | [a] Bicor [AL] | |

## ▪ METOPROLOL SUCCINATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8732N NP | 1 | .. | .. | 17.99 | 19.39 | [a] Metrol-XL 23.75 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF] |

**METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8733P NP | 1 | 5 | .. | 36.28 | 30.00 | [a] Metrol-XL 47.5 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 47.5 [AP] |

**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8734Q NP | 1 | 5 | .. | 42.08 | 30.00 | [a] Metrol-XL 95 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 95 [AP] |

**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8735R NP | 1 | 5 | .. | 49.36 | 30.00 | [a] Metrol-XL 190 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 190 [AP] |

## ▪ METOPROLOL SUCCINATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13543T NP | 2 | 5 | .. | *59.57 | 30.00 | [a] Metrol-XL 47.5 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 47.5 [AP] |

**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13544W NP | 2 | 5 | .. | *71.17 | 30.00 | [a] Metrol-XL 95 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 95 [AP] |

**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13420H NP | 2 | 5 | .. | *85.73 | 30.00 | [a] Metrol-XL 190 [RW]<br>[a] Topreloc-XL [CR] | [a] Minax XL [AF]<br>[a] Toprol-XL 190 [AP] |

## ▪ METOPROLOL TARTRATE

**METOPROLOL TARTRATE Tablet 100 mg, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1325R NP | 1 | 5 | .. | 15.96 | 17.36 | Mistrom [ZS]<br>[a] APO-Metoprolol [TX]<br>[a] Metrol 100 [RW]<br>[a] NOUMED METOPROLOL [VO] | [a] Metoprolol Sandoz [SZ]<br>[a] Minax 100 [AF] |
| | | | [B]13.15 | 29.11 | 17.36 | [a] Betaloc [AP] | |

**METOPROLOL TARTRATE Tablet 50 mg, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1324Q NP | 1 | 5 | .. | 15.70 | 17.10 | Mistrom [ZS]<br>[a] APO-Metoprolol [TX]<br>[a] Metrol 50 [RW]<br>[a] NOUMED METOPROLOL [VO] | [a] Metoprolol Sandoz [SZ]<br>[a] Minax 50 [AF] |
| | | | [B]13.15 | 28.85 | 17.10 | [a] Betaloc [AP] | |

## ▪ METOPROLOL TARTRATE

**Restricted benefit**

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

**METOPROLOL TARTRATE Tablet 100 mg, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13541Q NP | 2 | 5 | .. | *18.93 | 20.33 | Mistrom [ZS]<br>[a] APO-Metoprolol [TX]<br>[a] Metrol 100 [RW]<br>[a] NOUMED METOPROLOL [VO] | [a] Metoprolol Sandoz [SZ]<br>[a] Minax 100 [AF] |
| | | | [B]26.30 | *45.23 | 20.33 | [a] Betaloc [AP] | |

**METOPROLOL TARTRATE Tablet 50 mg, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13598Q NP | 2 | 5 | .. | *18.41 | 19.81 | Mistrom [ZS]<br>[a] APO-Metoprolol [TX]<br>[a] Metrol 50 [RW]<br>[a] NOUMED METOPROLOL [VO] | [a] Metoprolol Sandoz [SZ]<br>[a] Minax 50 [AF] |
| | | | [B]26.30 | *44.71 | 19.81 | [a] Betaloc [AP] | |

## ▪ NEBIVOLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9316H NP | 2 | 5 | .. | *38.27 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

**nebivolol 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9312D NP | 1 | 5 | .. | 48.68 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

**nebivolol 5 mg tablet, 28**

| 9311C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 44.57 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

## ▪ NEBIVOLOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

| 13568D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *63.57 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

**nebivolol 10 mg tablet, 28**

| 13441K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *84.37 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

**nebivolol 5 mg tablet, 28**

| 13510C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *76.15 | 30.00 | [a] APO-Nebivolol [TX]<br>[a] Nebivolol Lupin [GQ]<br>[a] Nepiten [AF] | [a] Nebilet [FK]<br>[a] Nebivolol Sandoz [SZ] |

*Alpha and beta blocking agents*

## ▪ CARVEDILOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**carvedilol 12.5 mg tablet, 60**

| 8257N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.22 | 22.62 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 12.5 [PB]<br>[a] Volirop 12.5 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 12.5 [RW] |

**carvedilol 25 mg tablet, 60**

| 8258P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.27 | 24.67 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 25 [PB]<br>[a] Volirop 25 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 25 [RW] |

**carvedilol 3.125 mg tablet, 30**

| 8255L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 16.73 | 18.13 | [a] APO-Carvedilol [TX]<br>[a] Vedilol 3.125 [RW] | [a] Carvidol [RF]<br>[a] Volirop 3.125 [ZS] |

**carvedilol 6.25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8256M NP | 1 | 5 | .. | 19.57 | 20.97 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 6.25 [PB]<br>[a] Volirop 6.25 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 6.25 [RW] |

## ▪ CARVEDILOL

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Clinical criteria:**

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

**carvedilol 12.5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13418F NP | 2 | 5 | .. | *29.45 | 30.00 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 12.5 [PB]<br>[a] Volirop 12.5 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 12.5 [RW] |

**carvedilol 25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13387N NP | 2 | 5 | .. | *33.55 | 30.00 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 25 [PB]<br>[a] Volirop 25 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 25 [RW] |

**carvedilol 6.25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13417E NP | 2 | 5 | .. | *26.15 | 27.55 | [a] APO-Carvedilol [TX]<br>[a] Carvidol [RF]<br>[a] Dilatrend 6.25 [PB]<br>[a] Volirop 6.25 [ZS] | [a] Carvedilol Sandoz [SZ]<br>[a] Dicarz [AF]<br>[a] Vedilol 6.25 [RW] |

## ▪ LABETALOL

**labetalol hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1566K NP | 1 | 5 | .. | 26.24 | 27.64 | Presolol 100 [AF] |

# ▪ CALCIUM CHANNEL BLOCKERS

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

*Dihydropyridine derivatives*

## ▪ AMLODIPINE

**amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2751T NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Amlo 5 [RW]<br>[a] Amlodipine APOTEX [GX]<br>[a] Amlodipine Sandoz [SZ]<br>[a] Blooms Amlodipine [BG]<br>[a] BTC Amlodipine [JB]<br>[a] Norvapine [ED]<br>[a] Pharmacor Amlodipine [CR] | [a] Amlodipine Amneal [EF]<br>[a] Amlodipine GH [GQ]<br>[a] APO-Amlodipine [TX]<br>[a] Blooms the Chemist Amlodipine [IB]<br>[a] Nordip [AF]<br>[a] NOUMED AMLODIPINE [VO] |
| | | | [B]11.17 | 26.87 | 17.10 | [a] Norvasc [AS] | |

**amlodipine 10 mg tablet, 30**

| 2752W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Amlo 10 [RW] | [a] Amlodipine Amneal [EF] |
| | | | | | | [a] Amlodipine APOTEX [GX] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] APO-Amlodipine [TX] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Blooms the Chemist Amlodipine [IB] |
| | | | | | | [a] BTC Amlodipine [JB] | [a] Nordip [AF] |
| | | | | | | [a] Norvapine [ED] | [a] NOUMED AMLODIPINE [VO] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]11.18 | 26.88 | 17.10 | [a] Norvasc [AS] | |

## ▪ AMLODIPINE

**Restricted benefit**

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

**amlodipine 5 mg tablet, 30**

| 13532F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Amlo 5 [RW] | [a] Amlodipine Amneal [EF] |
| | | | | | | [a] Amlodipine APOTEX [GX] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] APO-Amlodipine [TX] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Blooms the Chemist Amlodipine [IB] |
| | | | | | | [a] BTC Amlodipine [JB] | [a] Nordip [AF] |
| | | | | | | [a] Norvapine [ED] | [a] NOUMED AMLODIPINE [VO] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]22.34 | *40.75 | 19.81 | [a] Norvasc [AS] | |

**amlodipine 10 mg tablet, 30**

| 13562T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Amlo 10 [RW] | [a] Amlodipine Amneal [EF] |
| | | | | | | [a] Amlodipine APOTEX [GX] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] APO-Amlodipine [TX] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Blooms the Chemist Amlodipine [IB] |
| | | | | | | [a] BTC Amlodipine [JB] | [a] Nordip [AF] |
| | | | | | | [a] Norvapine [ED] | [a] NOUMED AMLODIPINE [VO] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]22.36 | *40.77 | 19.81 | [a] Norvasc [AS] | |

## ▪ FELODIPINE

**felodipine 10 mg modified release tablet, 30**

| 2367N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.29 | 21.69 | [a] Felodil XR 10 [RW] | [a] Felodur ER 10 mg [TX] |
| | | | | | | [a] Fendex ER [AF] | |
| | | | [B]3.75 | 24.04 | 21.69 | [a] Plendil ER [GX] | |

**felodipine 2.5 mg modified release tablet, 30**

| 2361G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.33 | 17.73 | [a] Felodur ER 2.5 mg [TX] | [a] Fendex ER [AF] |
| | | | [B]3.97 | 20.30 | 17.73 | [a] Plendil ER [GX] | |

**felodipine 5 mg modified release tablet, 30**

| 2366M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.02 | 18.42 | [a] Felodil XR 5 [RW] | [a] Felodur ER 5 mg [TX] |
| | | | | | | [a] Fendex ER [AF] | |
| | | | [B]3.88 | 20.90 | 18.42 | [a] Plendil ER [GX] | |

## ▪ FELODIPINE

**Restricted benefit**

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

**felodipine 10 mg modified release tablet, 30**

| 13531E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *27.59 | 28.99 | [a] Felodil XR 10 [RW] | [a] Felodur ER 10 mg [TX] |
| | | | | | | [a] Fendex ER [AF] | |
| | | | [B]7.50 | *35.09 | 28.99 | [a] Plendil ER [GX] | |

**felodipine 2.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13377C NP | 2 | 5 | .. | *19.67 | 21.07 | [a] Felodur ER 2.5 mg [TX] | [a] Fendex ER [AF] |
| | | | [B]7.94 | *27.61 | 21.07 | [a] Plendil ER [GX] | |

**felodipine 5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13561R NP | 2 | 5 | .. | *21.05 | 22.45 | [a] Felodil XR 5 [RW]<br>[a] Fendex ER [AF] | [a] Felodur ER 5 mg [TX] |
| | | | [B]7.76 | *28.81 | 22.45 | [a] Plendil ER [GX] | |

## ▪ LERCANIDIPINE

**lercanidipine hydrochloride 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8534E NP | 1 | 5 | .. | 15.70 | 17.10 | [a] BTC Lercanidipine [JB]<br>[a] Zircol 10 [AL] | [a] Lercanidipine APOTEX [GX] |
| | | | [B]3.48 | 19.18 | 17.10 | [a] Zanidip [GO] | |

**lercanidipine hydrochloride 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8679T NP | 1 | 5 | .. | 16.75 | 18.15 | [a] BTC Lercanidipine [JB]<br>[a] Zircol 20 [AL] | [a] Lercanidipine APOTEX [GX] |
| | | | [B]3.50 | 20.25 | 18.15 | [a] Zanidip [GO] | |

## ▪ LERCANIDIPINE

**Restricted benefit**

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

**lercanidipine hydrochloride 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13411W NP | 2 | 5 | .. | *18.41 | 19.81 | [a] BTC Lercanidipine [JB]<br>[a] Zircol 10 [AL] | [a] Lercanidipine APOTEX [GX] |
| | | | [B]6.96 | *25.37 | 19.81 | [a] Zanidip [GO] | |

**lercanidipine hydrochloride 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13412X NP | 2 | 5 | .. | *20.51 | 21.91 | [a] BTC Lercanidipine [JB]<br>[a] Zircol 20 [AL] | [a] Lercanidipine APOTEX [GX] |
| | | | [B]7.00 | *27.51 | 21.91 | [a] Zanidip [GO] | |

## ▪ NIFEDIPINE

**nifedipine 30 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1906H NP | 1 | 5 | .. | 19.88 | 21.28 | [a] Addos XR 30 [RW] | [a] APO-Nifedipine XR [TX] |

**nifedipine 60 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1907J NP | 1 | 5 | .. | 21.65 | 23.05 | [a] Addos XR 60 [RW] | [a] APO-Nifedipine XR [TX] |

## ▪ NIFEDIPINE

**Restricted benefit**

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

**nifedipine 30 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13502P NP | 2 | 5 | .. | *26.77 | 28.17 | [a] Addos XR 30 [RW] | [a] APO-Nifedipine XR [TX] |

**nifedipine 60 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13376B NP | 2 | 5 | .. | *30.31 | 30.00 | [a] Addos XR 60 [RW] | [a] APO-Nifedipine XR [TX] |

# SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

*Phenylalkylamine derivatives*

## ▪ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**verapamil hydrochloride 180 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2208F NP | 1 | 5 | .. | 18.33 | 19.73 | [a] Cordilox 180 SR [GT] |
| | | | [B]3.54 | 21.87 | 19.73 | [a] Isoptin 180 SR [GO] |

**verapamil hydrochloride 240 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1241H NP | 1 | 5 | .. | 20.12 | 21.52 | [a] Cordilox SR [GT] |
| | | | [B]3.50 | 23.62 | 21.52 | [a] Isoptin SR [GO] |

**verapamil hydrochloride 80 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1250T NP | 1 | 5 | .. | 19.61 | 21.01 | [a] Anpec 80 [AF] |
| | | | [B]3.10 | 22.71 | 21.01 | [a] Isoptin [GO] |

## ▪ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**Restricted benefit**

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

**verapamil hydrochloride 180 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13434C NP | 2 | 5 | .. | *23.67 | 25.07 | [a] Cordilox 180 SR [GT] |
| | | | [B]7.08 | *30.75 | 25.07 | [a] Isoptin 180 SR [GO] |

**verapamil hydrochloride 240 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13408Q NP | 2 | 5 | .. | *27.25 | 28.65 | [a] Cordilox SR [GT] |
| | | | [B]7.00 | *34.25 | 28.65 | [a] Isoptin SR [GO] |

**verapamil hydrochloride 80 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13530D NP | 2 | 5 | .. | *26.23 | 27.63 | [a] Anpec 80 [AF] |
| | | | [B]6.20 | *32.43 | 27.63 | [a] Isoptin [GO] |

*Benzothiazepine derivatives*

## ▪ DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**diltiazem hydrochloride 180 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1312C NP | 1 | 5 | .. | 19.71 | 21.11 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 21.61 | 21.11 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 240 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1313D NP | 1 | 5 | .. | 22.08 | 23.48 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 23.98 | 23.48 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 360 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8480H NP | 1 | 5 | .. | 24.90 | 26.30 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.90 | 26.80 | 26.30 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 60 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1335G NP | 1 | 5 | .. | 20.95 | 22.35 | [a] Diltiazem AN [EA] | [a] Vasocardol [AV] |
| | | | [B]1.90 | 22.85 | 22.35 | [a] Cardizem [SW] | |

# ▪ AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

## ACE INHIBITORS, PLAIN

*ACE inhibitors, plain*

## ▪ CAPTOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Patients unable to take a solid dose form of an ACE inhibitor.

**captopril 5 mg/mL oral liquid, 95 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8760C NP | ‡1 | 5 | .. | 108.81 | 30.00 | Capoten [RW] |

## ▪ ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**enalapril maleate 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1368B NP | 1 | 5 | .. | 16.61 | 18.01 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]10.41 | 27.02 | 18.01 | [a] Renitec [AF] | |

**enalapril maleate 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1369C NP | 1 | 5 | .. | 16.91 | 18.31 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]10.40 | 27.31 | 18.31 | [a] Renitec 20 [AF] | |

**enalapril maleate 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1370D NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |

## ▪ ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

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

**enalapril maleate 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13465Q NP | 2 | 5 | .. | *20.23 | 21.63 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]20.82 | *41.05 | 21.63 | [a] Renitec [AF] | |

**enalapril maleate 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13401H NP | 2 | 5 | .. | *20.83 | 22.23 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |
| | | | [B]20.80 | *41.63 | 22.23 | [a] Renitec 20 [AF] | |

**enalapril maleate 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13369P NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Acetec [AL]<br>[a] Enalapril generichealth [GQ]<br>[a] Malean [RW] | [a] APO-Enalapril [TX]<br>[a] Enalapril Sandoz [SZ] |

## ▪ FOSINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**fosinopril sodium 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1182F NP | 1 | 5 | .. | 17.58 | 18.98 | [a] APO-Fosinopril [TX] | [a] Monace 10 [AF] |

**fosinopril sodium 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1183G NP | 1 | 5 | .. | 19.70 | 21.10 | [a] APO-Fosinopril [TX] | [a] Monace 20 [AF] |

## ▪ LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**lisinopril 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2457H NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Lisinopril [TX]<br>[a] Lisinopril Sandoz [SZ] | [a] Fibsol 10 [RW]<br>[a] Zinopril 10 [AL] |
| | | | [B]4.84 | 21.59 | 18.15 | [a] Zestril [IX] | |

**lisinopril 20 mg tablet, 30**

| 2458J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.07 | 18.47 | [a] APO-Lisinopril [TX] | [a] Fibsol 20 [RW] |
| | | | | | | [a] Lisinopril generichealth [GQ] | [a] Lisinopril Sandoz [SZ] |
| | | | | | | [a] Zinopril 20 [AL] | |
| | | | [B]4.83 | 21.90 | 18.47 | [a] Zestril [IX] | |

**lisinopril 5 mg tablet, 30**

| 2456G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.71 | 17.11 | [a] APO-Lisinopril [TX] | [a] Fibsol 5 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] Zinopril 5 [AL] |
| | | | [B]4.82 | 20.53 | 17.11 | [a] Zestril [IX] | |

## ▪ LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

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

**lisinopril 10 mg tablet, 30**

| 13584Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Lisinopril [TX] | [a] Fibsol 10 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] Zinopril 10 [AL] |
| | | | [B]9.68 | *30.19 | 21.91 | [a] Zestril [IX] | |

**lisinopril 20 mg tablet, 30**

| 13402J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.15 | 22.55 | [a] APO-Lisinopril [TX] | [a] Fibsol 20 [RW] |
| | | | | | | [a] Lisinopril generichealth [GQ] | [a] Lisinopril Sandoz [SZ] |
| | | | | | | [a] Zinopril 20 [AL] | |
| | | | [B]9.66 | *30.81 | 22.55 | [a] Zestril [IX] | |

**lisinopril 5 mg tablet, 30**

| 13583X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.43 | 19.83 | [a] APO-Lisinopril [TX] | [a] Fibsol 5 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] Zinopril 5 [AL] |
| | | | [B]9.64 | *28.07 | 19.83 | [a] Zestril [IX] | |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 2.5 mg tablet, 30**

| 9006B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] PREXUM 2.5 [RX] | |
| | | | [B]9.74 | 25.44 | 17.10 | [a] Coversyl 2.5mg [SE] | |

**perindopril erbumine 2 mg tablet, 30**

| 3050M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Perindopril [TX] | [a] Blooms the Chemist Perindopril [IB] |
| | | | | | | [a] BTC Perindopril [JB] | [a] Idaprex 2 [SZ] |
| | | | | | | [a] Indosyl Mono 2 [RW] | [a] Perindo [AF] |
| | | | | | | [a] PERISYL [AL] | |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 5 mg tablet, 30**

| 9007C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.39 | 17.79 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] PREXUM 5 [RX] | |
| | | | [B]9.45 | 25.84 | 17.79 | [a] Coversyl 5mg [SE] | |

**perindopril erbumine 4 mg tablet, 30**

| 3051N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.39 | 17.79 | [a] APO-Perindopril [TX] | [a] Blooms the Chemist Perindopril [IB] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] BTC Perindopril [JB] | [a] Idaprex 4 [SZ] |
| | | | | | | [a] Indosyl Mono 4 [RW] | [a] Perindo [AF] |
| | | | | | | [a] Perindopril generichealth [GQ] | [a] PERISYL [AL] |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 10 mg tablet, 30**

| 9008D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.37 | 18.77 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] PREXUM 10 [RX] | |
| | | | [B]9.92 | 27.29 | 18.77 | [a] Coversyl 10mg [SE] | |

**perindopril erbumine 8 mg tablet, 30**

| 8704D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.37 | 18.77 | [a] APO-Perindopril [TX] | [a] Blooms the Chemist Perindopril [IB] |
| | | | | | | [a] BTC Perindopril [JB] | [a] Idaprex 8 [SZ] |
| | | | | | | [a] Indosyl Mono 8 [RW] | [a] Perindo [AF] |
| | | | | | | [a] Perindopril generichealth [GQ] | [a] PERISYL [AL] |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

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

**perindopril arginine 5 mg tablet, 30**

| 13585B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *19.79 | 21.19 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] PREXUM 5 [RX] | |
| | | | [B]18.90 | *38.69 | 21.19 | [a] Coversyl 5mg [SE] | |

**perindopril erbumine 4 mg tablet, 30**

| 13371R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *19.79 | 21.19 | [a] APO-Perindopril [TX] | [a] Blooms the Chemist Perindopril [IB] |
| | | | | | | [a] BTC Perindopril [JB] | [a] Idaprex 4 [SZ] |
| | | | | | | [a] Indosyl Mono 4 [RW] | [a] Perindo [AF] |
| | | | | | | [a] Perindopril generichealth [GQ] | [a] PERISYL [AL] |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

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

**perindopril arginine 10 mg tablet, 30**

| 13555K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.75 | 23.15 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] PREXUM 10 [RX] | |
| | | | [B]19.84 | *41.59 | 23.15 | [a] Coversyl 10mg [SE] | |

**perindopril erbumine 8 mg tablet, 30**

| 13372T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.75 | 23.15 | [a] APO-Perindopril [TX] | [a] Blooms the Chemist Perindopril [IB] |
| | | | | | | [a] BTC Perindopril [JB] | [a] Idaprex 8 [SZ] |
| | | | | | | [a] Indosyl Mono 8 [RW] | [a] Perindo [AF] |
| | | | | | | [a] Perindopril generichealth [GQ] | [a] PERISYL [AL] |

## ▪ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

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

**perindopril arginine 2.5 mg tablet, 30**

13494F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Perindopril Arginine [TX]<br>[a] PREXUM 2.5 [RX] | [a] APX-Perindopril Arginine [XT] |
| | | [B]19.48 | *37.89 | 19.81 | [a] Coversyl 2.5mg [SE] | |

**perindopril erbumine 2 mg tablet, 30**

13404L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Perindopril [TX]<br>[a] BTC Perindopril [JB]<br>[a] Indosyl Mono 2 [RW]<br>[a] PERISYL [AL] | [a] Blooms the Chemist Perindopril [IB]<br>[a] Idaprex 2 [SZ]<br>[a] Perindo [AF] |

## ▪ QUINAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**quinapril 20 mg tablet, 30**

1970Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.98 | 19.38 | [a] ACQUIN [RF]<br>[a] Qpril 20 [AF] | [a] APO-Quinapril [TX] |
| | | [B]4.20 | 22.18 | 19.38 | [a] Accupril [PF] | |

**quinapril 5 mg tablet, 30**

1968N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.81 | 18.21 | [a] ACQUIN [RF] | [a] Qpril 5 [AF] |
| | | [B]4.05 | 20.86 | 18.21 | [a] Accupril [PF] | |

**quinapril 10 mg tablet, 30**

1969P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.11 | 18.51 | [a] ACQUIN [RF]<br>[a] Qpril 10 [AF] | [a] APO-Quinapril [TX] |
| | | [B]4.07 | 21.18 | 18.51 | [a] Accupril [PF] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**ramipril 10 mg capsule, 30**

8470T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Ramipril [TX]<br>[a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Caps 10 [AF] | [a] APX-Ramipril [TY]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 10 mg [SW] |

**ramipril 10 mg tablet, 30**

1316G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Ramipril [TX]<br>[a] Tritace [SW] | [a] Ramipril Sandoz [SZ]<br>[a] Tryzan Tabs 10 [AF] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**ramipril 1.25 mg capsule, 30**

9120B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 1.25 [AF] |

**ramipril 1.25 mg tablet, 30**

1944H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Tabs 1.25 [AF] | [a] Ramipril Sandoz [SZ]<br>[a] Tritace 1.25 mg [SW] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**ramipril 2.5 mg capsule, 30**

9121C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 2.5 [AF] |

**ramipril 2.5 mg tablet, 30**

1945J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Ramipril [TX]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 2.5 mg [SW] | [a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Tabs 2.5 [AF] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**ramipril 5 mg capsule, 30**

9122D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 5 [AF] |

**ramipril 5 mg tablet, 30**

1946K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Ramipril [TX]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 5 mg [SW] | [a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Tabs 5 [AF] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

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

**ramipril 10 mg capsule, 30**

13430W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Ramipril [TX]<br>[a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Caps 10 [AF] | [a] APX-Ramipril [TY]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 10 mg [SW] |

**ramipril 10 mg tablet, 30**

13368N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Ramipril [TX]<br>[a] Tritace [SW] | [a] Ramipril Sandoz [SZ]<br>[a] Tryzan Tabs 10 [AF] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

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

**ramipril 2.5 mg capsule, 30**

13405M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 2.5 [AF] |

**ramipril 2.5 mg tablet, 30**

13466R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Ramipril [TX]<br>[a] Ramipril Sandoz [SZ]<br>[a] Tritace 2.5 mg [SW] | [a] Prilace [RF]<br>[a] Ramipril Winthrop [WA]<br>[a] Tryzan Tabs 2.5 [AF] |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

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

**ramipril 1.25 mg capsule, 30**

13431X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 1.25 [AF] |

**ramipril 1.25 mg tablet, 30**

13582W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] Prilace [RF] | [a] Ramipril Sandoz [SZ] |
| | | | | | [a] Ramipril Winthrop [WA] | [a] Tritace 1.25 mg [SW] |
| | | | | | [a] Tryzan Tabs 1.25 [AF] | |

## ▪ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

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

**ramipril 5 mg capsule, 30**

13556L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 5 [AF] |

**ramipril 5 mg tablet, 30**

13526X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Ramipril [TX] | [a] Prilace [RF] |
| | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Winthrop [WA] |
| | | | | | [a] Tritace 5 mg [SW] | [a] Tryzan Tabs 5 [AF] |

## ▪ TRANDOLAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**trandolapril 1 mg capsule, 28**

2792Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.96 | 18.36 | [a] Dolapril 1 [RW] | [a] Tranalpha [AF] |
| | | [B]3.50 | 20.46 | 18.36 | [a] Gopten [GO] | |

**trandolapril 2 mg capsule, 28**

2793B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.77 | 19.17 | [a] Dolapril 2 [RW] | [a] Tranalpha [AF] |
| | | [B]3.50 | 21.27 | 19.17 | [a] Gopten [GO] | |

**trandolapril 4 mg capsule, 28**

8758Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.98 | 23.38 | [a] Dolapril 4 [RW] | [a] Tranalpha [AF] |
| | | [B]3.49 | 25.47 | 23.38 | [a] Gopten [GO] | |

**trandolapril 500 microgram capsule, 28**

2791X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] Dolapril 0.5 [RW] | [a] Tranalpha [AF] |
| | | [B]3.48 | 19.18 | 17.10 | [a] Gopten [GO] | |

## ▪ TRANDOLAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

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

**trandolapril 1 mg capsule, 28**

13429T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.93 | 22.33 | [a] Dolapril 1 [RW] | [a] Tranalpha [AF] |
| | | [B]7.00 | *27.93 | 22.33 | [a] Gopten [GO] | |

**trandolapril 2 mg capsule, 28**

13403K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *22.55 | 23.95 | [a] Dolapril 2 [RW] | [a] Tranalpha [AF] |
| | | [B]7.00 | *29.55 | 23.95 | [a] Gopten [GO] | |

**trandolapril 4 mg capsule, 28**

13467T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *30.97 | 30.00 | [a] Dolapril 4 [RW] | [a] Tranalpha [AF] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]6.98 | *37.95 | 30.00 | [a] Gopten [GO] | |

NP **andolapril 500 microgram capsule, 28**

13554J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] Dolapril 0.5 [RW] | [a] Tranalpha [AF] |
| | | [B]6.96 | *25.37 | 19.81 | [a] Gopten [GO] | |

## ACE INHIBITORS, COMBINATIONS

*ACE inhibitors and diuretics*

### ▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

8477E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.36 | 19.76 | [a] Enalapril/HCT Sandoz [SZ] | [a] Renitec Plus 20/6 [AF] |

### ▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

13439H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *23.73 | 25.13 | [a] Enalapril/HCT Sandoz [SZ] | [a] Renitec Plus 20/6 [AF] |

### ▪ FOSINOPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8401E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 21.39 | 22.79 | Fosetic 20/12.5 [ZP] |

### ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

2190G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] PREXUM Combi LD 2.5/0.625 [RX] |
| | | [B]7.86 | 23.56 | 17.10 | [a] Coversyl Plus LD 2.5mg/0.625mg [SE] |

### ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

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

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

| 13413Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] PREXUM Combi LD 2.5/0.625 [RX] |
| | | | [B]15.72 | *34.13 | 19.81 | [a] Coversyl Plus LD 2.5mg/0.625mg [SE] |

## ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 8449Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Perindopril/Indapamide [TX] | [a] GenRx Perindopril/ Indapamide 4/1.25 [GX] |
| | | | | | | [a] Idaprex Combi 4/1.25 [SZ] | [a] Indosyl Combi 4/1.25 [RW] |
| | | | | | | [a] Perindo Combi 4/1.25 [AF] | [a] PERISYL COMBI 4/1.25 [AL] |

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 2845R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] Prexum Combi 5/1.25 [RX] |
| | | | [B]7.14 | 23.89 | 18.15 | [a] Coversyl Plus 5mg/1.25mg [SE] |

## ▪ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 13476G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Perindopril/Indapamide [TX] | [a] GenRx Perindopril/ Indapamide 4/1.25 [GX] |
| | | | | | | [a] Idaprex Combi 4/1.25 [SZ] | [a] Indosyl Combi 4/1.25 [RW] |
| | | | | | | [a] Perindo Combi 4/1.25 [AF] | [a] PERISYL COMBI 4/1.25 [AL] |

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 13506W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.51 | 21.91 | [a] Prexum Combi 5/1.25 [RX] |
| | | | [B]14.28 | *34.79 | 21.91 | [a] Coversyl Plus 5mg/1.25mg [SE] |

## ▪ QUINAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8589C NP | 1 | 5 | .. | 18.57 | 19.97 | Accuretic 10/12.5mg [PF] |

**quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8590D NP | 1 | 5 | .. | 19.48 | 20.88 | Accuretic 20/12.5mg [PF] |

*ACE inhibitors and calcium channel blockers*

## ▪ LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9144G NP | 1 | 5 | .. | 17.97 | 19.37 | Zan-Extra 10/10 [GO] |

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9145H NP | 1 | 5 | .. | 18.75 | 20.15 | Zan-Extra 10/20 [GO] |

## ▪ LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13507X NP | 2 | 5 | .. | *22.95 | 24.35 | Zan-Extra 10/10 [GO] |

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13477H NP | 2 | 5 | .. | *24.51 | 25.91 | Zan-Extra 10/20 [GO] |

## ▪ PERINDOPRIL + AMLODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9349C NP | 1 | 5 | .. | 18.95 | 20.35 | [a] APO-Perindopril Arginine/Amlodipine 10/10 [TX]<br>[a] Reaptan 10/10 [RX] | [a] APX-Perindopril Arginine/Amlodipine 10/10 [XT] |
| | | | [B]9.85 | 28.80 | 20.35 | [a] Coveram 10/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9348B NP | 1 | 5 | .. | 18.26 | 19.66 | [a] APO-Perindopril Arginine/Amlodipine 10/5 [TX]<br>[a] Reaptan 10/5 [RX] | [a] APX-Perindopril Arginine/Amlodipine 10/5 [XT] |
| | | | [B]9.54 | 27.80 | 19.66 | [a] Coveram 10/5 [SE] | |

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9347Y NP | 1 | 5 | .. | 17.43 | 18.83 | [a] APO-Perindopril Arginine/Amlodipine 5/10 [TX]<br>[a] Reaptan 5/10 [RX] | [a] APX-Perindopril Arginine/Amlodipine 5/10 [XT] |
| | | | [B]9.39 | 26.82 | 18.83 | [a] Coveram 5/10 [SE] | |

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9346X NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Perindopril Arginine/Amlodipine 5/5 [TX]<br>[a] Reaptan 5/5 [RX] | [a] APX-Perindopril Arginine/Amlodipine 5/5 [XT] |
| | | | [B]9.08 | 25.83 | 18.15 | [a] Coveram 5/5 [SE] | |

## ▪ PERINDOPRIL + AMLODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13382H NP | 2 | 5 | .. | *24.91 | 26.31 | [a] APO-Perindopril Arginine/Amlodipine 10/10 [TX]<br>[a] Reaptan 10/10 [RX] | [a] APX-Perindopril Arginine/Amlodipine 10/10 [XT] |
| | | | [B]19.70 | *44.61 | 26.31 | [a] Coveram 10/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13478J NP | 2 | 5 | .. | *23.53 | 24.93 | [a] APO-Perindopril Arginine/Amlodipine 10/5 [TX]<br>[a] Reaptan 10/5 [RX] | [a] APX-Perindopril Arginine/Amlodipine 10/5 [XT] |
| | | | [B]19.08 | *42.61 | 24.93 | [a] Coveram 10/5 [SE] | |

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13381G NP | 2 | 5 | .. | *21.87 | 23.27 | [a] APO-Perindopril Arginine/Amlodipine 5/10 [TX]<br>[a] Reaptan 5/10 [RX] | [a] APX-Perindopril Arginine/Amlodipine 5/10 [XT] |
| | | | [B]18.78 | *40.65 | 23.27 | [a] Coveram 5/10 [SE] | |

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13508Y NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Perindopril Arginine/Amlodipine 5/5 [TX]<br>[a] Reaptan 5/5 [RX] | [a] APX-Perindopril Arginine/Amlodipine 5/5 [XT] |
| | | | [B]18.16 | *38.67 | 21.91 | [a] Coveram 5/5 [SE] | |

## ▪ RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2626F NP | 1 | 5 | .. | 17.29 | 18.69 | Triasyn 2.5/2.5 [SW] |

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2629J NP | 1 | 5 | .. | 18.89 | 20.29 | Triasyn 5.0/5.0 [SW] |

## ▪ RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13563W NP | 2 | 5 | .. | *21.59 | 22.99 | Triasyn 2.5/2.5 [SW] |

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13534H NP | 2 | 5 | .. | *24.79 | 26.19 | Triasyn 5.0/5.0 [SW] |

## ▪ TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9387C NP | 1 | 5 | .. | 23.41 | 24.81 | Tarka 2/180 [GO] |

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2857J NP | 1 | 5 | .. | 29.48 | 30.00 | Tarka 4/240 [GO] |

## ▪ TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13594L NP | 2 | 5 | .. | *33.83 | 30.00 | Tarka 2/180 [GO] |

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

| 13591H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *45.97 | 30.00 | Tarka 4/240 [GO] |

## ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

*Angiotensin II receptor blockers (ARBs), plain*

### ▪ CANDESARTAN

**candesartan cilexetil 8 mg tablet, 30**

| 8296P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]13.45 | 29.15 | 17.10 | [a] Atacand [AP] | |

**candesartan cilexetil 16 mg tablet, 30**

| 8297Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.12 | 18.52 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]13.47 | 30.59 | 18.52 | [a] Atacand [AP] | |

**candesartan cilexetil 32 mg tablet, 30**

| 8889W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.29 | 18.69 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]11.61 | 28.90 | 18.69 | [a] Atacand [AP] | |

**candesartan cilexetil 4 mg tablet, 30**

| 8295N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]13.45 | 29.15 | 17.10 | [a] Atacand [AP] | |

### ▪ CANDESARTAN

**Restricted benefit**

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

**candesartan cilexetil 8 mg tablet, 30**

| 13436E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]26.90 | *45.31 | 19.81 | [a] Atacand [AP] | |

**candesartan cilexetil 16 mg tablet, 30**

| 13565Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.25 | 22.65 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan [IB] | [a] BTC Candesartan [BG] |
| | | | | | | [a] CANDESAN [RF] | [a] Candesartan Sandoz [SZ] |
| | | | | | | [a] NOUMED CANDESARTAN [VO] | |
| | | | [B]26.94 | *48.19 | 22.65 | [a] Atacand [AP] | |

**candesartan cilexetil 32 mg tablet, 30**

| 13438G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.59 | 22.99 | [a] Adesan [AF]<br>[a] Blooms the Chemist Candesartan [IB]<br>[a] CANDESAN [RF]<br>[a] NOUMED CANDESARTAN [VO] | [a] APO-Candesartan [TX]<br>[a] BTC Candesartan [BG]<br>[a] Candesartan Sandoz [SZ] |
| | | | [B]23.22 | *44.81 | 22.99 | [a] Atacand [AP] | |

**candesartan cilexetil 4 mg tablet, 30**

| 13592J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Adesan [AF]<br>[a] Blooms the Chemist Candesartan [IB]<br>[a] CANDESAN [RF]<br>[a] NOUMED CANDESARTAN [VO] | [a] APO-Candesartan [TX]<br>[a] BTC Candesartan [BG]<br>[a] Candesartan Sandoz [SZ] |
| | | | [B]26.90 | *45.31 | 19.81 | [a] Atacand [AP] | |

## ▪ EPROSARTAN

**eprosartan 600 mg tablet, 28**

| 8447N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | [T]2.62 | 27.27 | 26.05 | Teveten [GO] |

## ▪ EPROSARTAN

**Authority required**

Adverse effects occurring with all of the base-priced drugs

**Authority required**

Drug interactions occurring with all of the base-priced drugs

**Authority required**

Drug interactions expected to occur with all of the base-priced drugs

**Authority required**

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

**eprosartan 600 mg tablet, 28**

| 5491B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.27 | 28.67 | Teveten [GO] |

## ▪ IRBESARTAN

**irbesartan 150 mg tablet, 30**

| 8247C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Abisart 150 [AL]<br>[a] AVSARTAN [RF]<br>[a] Irbesartan GH [GQ]<br>[a] Noumed Irbesartan [VO] | [a] APO-Irbesartan [TX]<br>[a] Blooms the Chemist Irbesartan [IB]<br>[a] Irbesartan Sandoz [SZ] |
| | | | [B]3.10 | 18.80 | 17.10 | [a] Avapro [AV] | [a] Karvea [SW] |

**irbesartan 300 mg tablet, 30**

| 8248D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] Abisart 300 [AL]<br>[a] AVSARTAN [RF]<br>[a] Irbesartan AN [EA]<br>[a] Irbesartan Sandoz [SZ] | [a] APO-Irbesartan [TX]<br>[a] Blooms the Chemist Irbesartan [IB]<br>[a] Irbesartan GH [GQ]<br>[a] Noumed Irbesartan [VO] |
| | | | [B]3.12 | 19.87 | 18.15 | [a] Avapro [AV] | [a] Karvea [SW] |

**irbesartan 75 mg tablet, 30**

| 8246B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Abisart 75 [AL]<br>[a] AVSARTAN [RF]<br>[a] Irbesartan AMNEAL [EF]<br>[a] Irbesartan GH [GQ]<br>[a] Noumed Irbesartan [VO] | [a] APO-Irbesartan [TX]<br>[a] Blooms the Chemist Irbesartan [IB]<br>[a] Irbesartan AN [EA]<br>[a] Irbesartan Sandoz [SZ] |
| | | | [B]3.10 | 18.80 | 17.10 | [a] Avapro [AV] | [a] Karvea [SW] |

## ▪ IRBESARTAN

**Restricted benefit**

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

**irbesartan 150 mg tablet, 30**

13380F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] Abisart 150 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | [a] AVSARTAN [RF] | [a] Blooms the Chemist Irbesartan [IB] |
| | | | | | [a] Irbesartan GH [GQ] | [a] Irbesartan Sandoz [SZ] |
| | | | | | [a] Noumed Irbesartan [VO] | |
| | | [B]6.20 | *24.61 | 19.81 | [a] Avapro [AV] | [a] Karvea [SW] |

**irbesartan 300 mg tablet, 30**

13564X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] Abisart 300 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | [a] AVSARTAN [RF] | [a] Blooms the Chemist Irbesartan [IB] |
| | | | | | [a] Irbesartan AN [EA] | [a] Irbesartan GH [GQ] |
| | | | | | [a] Irbesartan Sandoz [SZ] | [a] Noumed Irbesartan [VO] |
| | | [B]6.24 | *26.75 | 21.91 | [a] Avapro [AV] | [a] Karvea [SW] |

**irbesartan 75 mg tablet, 30**

13435D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] Abisart 75 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | [a] AVSARTAN [RF] | [a] Blooms the Chemist Irbesartan [IB] |
| | | | | | [a] Irbesartan AMNEAL [EF] | [a] Irbesartan AN [EA] |
| | | | | | [a] Irbesartan GH [GQ] | [a] Irbesartan Sandoz [SZ] |
| | | | | | [a] Noumed Irbesartan [VO] | |
| | | [B]6.20 | *24.61 | 19.81 | [a] Avapro [AV] | [a] Karvea [SW] |

## ▪ OLMESARTAN

**olmesartan medoxomil 20 mg tablet, 30**

2147B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.11 | 18.51 | [a] APO-Olmesartan [TX] | [a] APX-Olmesartan [TY] |
| | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | [a] Olmesartan Sandoz [SZ] | [a] Olsetan [MQ] |
| | | | | | [a] Pharmacor Olmesartan 20 [CR] | |
| | | [B]3.50 | 20.61 | 18.51 | [a] Olmetec [AL] | |

**olmesartan medoxomil 40 mg tablet, 30**

2148C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 20.46 | 21.86 | [a] APO-Olmesartan [TX] | [a] APX-Olmesartan [TY] |
| | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | [a] Olmesartan Sandoz [SZ] | [a] Olsetan [MQ] |
| | | | | | [a] Pharmacor Olmesartan 40 [CR] | |
| | | [B]3.00 | 23.46 | 21.86 | [a] Olmetec [AL] | |

## ▪ OLMESARTAN

**Restricted benefit**

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

**olmesartan medoxomil 20 mg tablet, 30**

13505T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.23 | 22.63 | [a] APO-Olmesartan [TX] | [a] APX-Olmesartan [TY] |
| | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | [a] Olmesartan Sandoz [SZ] | [a] Olsetan [MQ] |
| | | | | | [a] Pharmacor Olmesartan 20 [CR] | |
| | | [B]7.00 | *28.23 | 22.63 | [a] Olmetec [AL] | |

**olmesartan medoxomil 40 mg tablet, 30**

13533G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *27.93 | 29.33 | [a] APO-Olmesartan [TX] | [a] APX-Olmesartan [TY] |
| | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | [a] Olmesartan Sandoz [SZ] | [a] Olsetan [MQ] |
| | | | | | [a] Pharmacor Olmesartan 40 [CR] | |
| | | [B]6.00 | *33.93 | 29.33 | [a] Olmetec [AL] | |

## ▪ TELMISARTAN

### telmisartan 40 mg tablet, 28

| 8355R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Telmisartan [TX]<br>[a] NOUMED TELMISARTAN [VO]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Teltartan [RW] | [a] Mizart [AF]<br>[a] Pharmacor Telmisartan 40 [CR]<br>[a] Telmisartan Sandoz [SZ] |
| | | | [B]5.58 | 21.28 | 17.10 | [a] Micardis [BY] | |

### telmisartan 80 mg tablet, 28

| 8356T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Telmisartan [TX]<br>[a] NOUMED TELMISARTAN [VO]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Teltartan [RW] | [a] Mizart [AF]<br>[a] Pharmacor Telmisartan 80 [CR]<br>[a] Telmisartan Sandoz [SZ] |
| | | | [B]4.48 | 21.77 | 18.69 | [a] Micardis [BY] | |

## ▪ TELMISARTAN

**Restricted benefit**

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

### telmisartan 40 mg tablet, 28

| 13437F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Telmisartan [TX]<br>[a] NOUMED TELMISARTAN [VO]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Teltartan [RW] | [a] Mizart [AF]<br>[a] Pharmacor Telmisartan 40 [CR]<br>[a] Telmisartan Sandoz [SZ] |
| | | | [B]11.16 | *29.57 | 19.81 | [a] Micardis [BY] | |

### telmisartan 80 mg tablet, 28

| 13593K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Telmisartan [TX]<br>[a] NOUMED TELMISARTAN [VO]<br>[a] Telmisartan-DRLA [RZ]<br>[a] Teltartan [RW] | [a] Mizart [AF]<br>[a] Pharmacor Telmisartan 80 [CR]<br>[a] Telmisartan Sandoz [SZ] |
| | | | [B]8.96 | *30.55 | 22.99 | [a] Micardis [BY] | |

## ▪ VALSARTAN

### valsartan 160 mg tablet, 28

| 9370E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.02 | 22.42 | [a] Dilart [AF] | [a] Diovan [NV] |

### valsartan 40 mg tablet, 28

| 9368C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 17.96 | 19.36 | [a] Dilart [AF] | [a] Diovan [NV] |

### valsartan 80 mg tablet, 28

| 9369D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.25 | 20.65 | [a] Dilart [AF] | [a] Diovan [NV] |

## ▪ VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

### valsartan 320 mg tablet, 28

| 9371F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.29 | 24.69 | [a] Dilart [AF] | [a] Diovan [NV] |

## ▪ VALSARTAN

**Restricted benefit**

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

**valsartan 160 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13566B NP | 2 | 5 | .. | *29.05 | 30.00 | [a] Dilart [AF] | [a] Diovan [NV] |

**valsartan 80 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13414B NP | 2 | 5 | .. | *25.51 | 26.91 | [a] Dilart [AF] | [a] Diovan [NV] |

## ▪ VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

**Restricted benefit**

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

**valsartan 320 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13383J NP | 2 | 5 | .. | *33.59 | 30.00 | [a] Dilart [AF] | [a] Diovan [NV] |

## ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

*Angiotensin II receptor blockers (ARBs) and diuretics*

## ▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8504N NP | 1 | 5 | .. | 17.29 | 18.69 | [a] Adesan HCT 16/12.5 [AF] | [a] APO-Candesartan HCTZ 16/12.5 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 16/12.5 [IB] | [a] CANDESAN COMBI 16/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]13.09 | 30.38 | 18.69 | [a] Atacand Plus 16/12.5 [AP] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9314F NP | 1 | 5 | .. | 17.29 | 18.69 | [a] Adesan HCT 32/12.5 [AF] | [a] APO-Candesartan HCTZ 32/12.5 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 32/12.5 [IB] | [a] CANDESAN COMBI 32/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]11.18 | 28.47 | 18.69 | [a] Atacand Plus 32/12.5 [AP] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9315G NP | 1 | 5 | .. | 17.83 | 19.23 | [a] Adesan HCT 32/25 [AF] | [a] APO-Candesartan HCTZ 32/25 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 32/25 [IB] | [a] CANDESAN COMBI 32/25 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]10.85 | 28.68 | 19.23 | [a] Atacand Plus 32/25 [AP] | |

## ▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13391T NP | 2 | 5 | .. | *21.59 | 22.99 | [a] Adesan HCT 16/12.5 [AF] | [a] APO-Candesartan HCTZ 16/12.5 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 16/12.5 [IB] | [a] CANDESAN COMBI 16/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]26.18 | *47.77 | 22.99 | [a] Atacand Plus 16/12.5 [AP] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13452B NP | 2 | 5 | .. | *21.59 | 22.99 | [a] Adesan HCT 32/12.5 [AF] | [a] APO-Candesartan HCTZ 32/12.5 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 32/12.5 [IB] | [a] CANDESAN COMBI 32/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]22.36 | *43.95 | 22.99 | [a] Atacand Plus 32/12.5 [AP] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13392W NP | 2 | 5 | .. | *22.67 | 24.07 | [a] Adesan HCT 32/25 [AF] | [a] APO-Candesartan HCTZ 32/25 [TX] |
| | | | | | | [a] Blooms the Chemist Candesartan HCTZ 32/25 [IB] | [a] CANDESAN COMBI 32/25 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] NOUMED CANDESARTAN/HCT [VO] |
| | | | [B]21.70 | *44.37 | 24.07 | [a] Atacand Plus 32/25 [AP] | |

## ▪ EPROSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8624X NP | 1 | 5 | .. | 25.78 | 27.18 | Teveten Plus 600/12.5 [GO] |

## ▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8404H NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Abisart HCTZ 150/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 150/12.5 [RF] | [a] Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] |
| | | | | | | [a] Irbesartan/HCT Sandoz [SZ] | |
| | | | [B]3.10 | 18.80 | 17.10 | [a] Avapro HCT 150/12.5 [AV] | [a] Karvezide 150/12.5 [SW] |

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8405J NP | 1 | 5 | .. | 16.86 | 18.26 | [a] Abisart HCTZ 300/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 300/12.5 [RF] | [a] Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] |
| | | | | | | [a] Irbesartan/HCT Sandoz [SZ] | |
| | | | [B]3.12 | 19.98 | 18.26 | [a] Avapro HCT 300/12.5 [AV] | [a] Karvezide 300/12.5 [SW] |

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2136K | 1 | 5 | .. | 17.20 | 18.60 | [a] Abisart HCTZ 300/25 [AL] | [a] APO-Irbesartan HCTZ [TX] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| NP | | | | | | [a] AVSARTAN HCT 300/25 [RF]<br>[a] Irbesartan/HCT Sandoz [SZ] | [a] Blooms the Chemist Irbesartan HCTZ 300/25 [IB] |
| | | | [B]3.12 | 20.32 | 18.60 | [a] Avapro HCT 300/25 [AV] | [a] Karvezide 300/25 [SW] |

## ▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

13572H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 5 | .. | *18.41 | 19.81 | [a] Abisart HCTZ 150/12.5 [AL]<br>[a] AVSARTAN HCT 150/12.5 [RF]<br>[a] Irbesartan/HCT Sandoz [SZ] | [a] APO-Irbesartan HCTZ [TX]<br>[a] Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] |
| | | [B]6.20 | *24.61 | 19.81 | [a] Avapro HCT 150/12.5 [AV] | [a] Karvezide 150/12.5 [SW] |

### irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

13545X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 5 | .. | *20.73 | 22.13 | [a] Abisart HCTZ 300/12.5 [AL]<br>[a] AVSARTAN HCT 300/12.5 [RF]<br>[a] Irbesartan/HCT Sandoz [SZ] | [a] APO-Irbesartan HCTZ [TX]<br>[a] Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] |
| | | [B]6.24 | *26.97 | 22.13 | [a] Avapro HCT 300/12.5 [AV] | [a] Karvezide 300/12.5 [SW] |

### irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

13446Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 5 | .. | *21.41 | 22.81 | [a] Abisart HCTZ 300/25 [AL]<br>[a] AVSARTAN HCT 300/25 [RF]<br>[a] Irbesartan/HCT Sandoz [SZ] | [a] APO-Irbesartan HCTZ [TX]<br>[a] Blooms the Chemist Irbesartan HCTZ 300/25 [IB] |
| | | [B]6.24 | *27.65 | 22.81 | [a] Avapro HCT 300/25 [AV] | [a] Karvezide 300/25 [SW] |

## ▪ OLMESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

2161R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Olmesartan/HCTZ 20/12.5 [TX]<br>[a] OLMERTAN COMBI 20/12.5 [RW]<br>[a] Olmesartan/HCT Sandoz [SZ] | [a] APX-Olmesartan/HCTZ [TY]<br>[a] Olmesartan HCT - MYL 20/12.5 [AF]<br>[a] Pharmacor Olmesartan HCTZ 20/12.5 [CR] |
| | | [B]1.39 | 18.68 | 18.69 | [a] Olmetec Plus [AL] | |

### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

2166B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 1 | 5 | .. | 20.63 | 22.03 | [a] APO-Olmesartan/HCTZ 40/12.5 [TX]<br>[a] OLMERTAN COMBI 40/12.5 [RW]<br>[a] Olmesartan/HCT Sandoz [SZ] | [a] APX-Olmesartan/HCTZ [TY]<br>[a] Olmesartan HCT - MYL 40/12.5 [AF]<br>[a] Pharmacor Olmesartan HCTZ 40/12.5 [CR] |
| | | [B]4.21 | 24.84 | 22.03 | [a] Olmetec Plus [AL] | |

### olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

2170F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 1 | 5 | .. | 21.63 | 23.03 | [a] APO-Olmesartan/HCTZ 40/25 [TX]<br>[a] OLMERTAN COMBI 40/25 [RW] | [a] APX-Olmesartan/HCTZ [TY]<br>[a] Olmesartan HCT - MYL 40/25 [AF] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Olmesartan/HCT Sandoz [SZ] | [a] Pharmacor Olmesartan HCTZ 40/25 [CR] |
| | | | [B]2.95 | 24.58 | 23.03 | [a] Olmetec Plus [AL] | |

## ▪ OLMESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13447R NP | 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Olmesartan/HCTZ 20/12.5 [TX] | [a] APX-Olmesartan/HCTZ [TY] |
| | | | | | | [a] OLMERTAN COMBI 20/12.5 [RW] | [a] Olmesartan HCT - MYL 20/12.5 [AF] |
| | | | | | | [a] Olmesartan/HCT Sandoz [SZ] | [a] Pharmacor Olmesartan HCTZ 20/12.5 [CR] |
| | | | [B]2.78 | *24.37 | 22.99 | [a] Olmetec Plus [AL] | |

### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13601W NP | 2 | 5 | .. | *28.27 | 29.67 | [a] APO-Olmesartan/HCTZ 40/12.5 [TX] | [a] APX-Olmesartan/HCTZ [TY] |
| | | | | | | [a] OLMERTAN COMBI 40/12.5 [RW] | [a] Olmesartan HCT - MYL 40/12.5 [AF] |
| | | | | | | [a] Olmesartan/HCT Sandoz [SZ] | [a] Pharmacor Olmesartan HCTZ 40/12.5 [CR] |
| | | | [B]8.42 | *36.69 | 29.67 | [a] Olmetec Plus [AL] | |

### olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13602X NP | 2 | 5 | .. | *30.27 | 30.00 | [a] APO-Olmesartan/HCTZ 40/25 [TX] | [a] APX-Olmesartan/HCTZ [TY] |
| | | | | | | [a] OLMERTAN COMBI 40/25 [RW] | [a] Olmesartan HCT - MYL 40/25 [AF] |
| | | | | | | [a] Olmesartan/HCT Sandoz [SZ] | [a] Pharmacor Olmesartan HCTZ 40/25 [CR] |
| | | | [B]5.90 | *36.17 | 30.00 | [a] Olmetec Plus [AL] | |

## ▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8622T NP | 1 | 5 | .. | 15.82 | 17.22 | [a] APO-Telmisartan HCTZ 40/12.5 [TX] | [a] Mizart HCT 40/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] Teltartan HCT 40/12.5 [RW] |
| | | | [B]5.54 | 21.36 | 17.22 | [a] Micardis Plus 40/12.5 mg [BY] | |

### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8623W NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Telmisartan HCTZ 80/12.5 [TX] | [a] Mizart HCT 80/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] Teltartan HCT 80/12.5 [RW] |
| | | | [B]4.01 | 21.30 | 18.69 | [a] Micardis Plus 80/12.5 mg [BY] | |

### telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9381R NP | 1 | 5 | .. | 17.62 | 19.02 | [a] APO-Telmisartan HCTZ 80/25 [TX] | [a] Mizart HCT 80/25 mg [AF] |
| | | | | | | [a] Telmisartan HCT GH 80/25 [GQ] | [a] Telmisartan/HCT Sandoz [SZ] |
| | | | | | | [a] Teltartan HCT 80/25 [RW] | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | [B]3.97 | 21.59 | 19.02 | [a] Micardis Plus 80/25 mg [BY] | |

## ▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13546Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.65 | 20.05 | [a] APO-Telmisartan HCTZ 40/12.5 [TX]<br>[a] Telmisartan/HCT Sandoz [SZ] | [a] Mizart HCT 40/12.5 mg [AF]<br>[a] Teltartan HCT 40/12.5 [RW] |
| | | [B]11.08 | *29.73 | 20.05 | [a] Micardis Plus 40/12.5 mg [BY] | |

**telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13574K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Telmisartan HCTZ 80/12.5 [TX]<br>[a] Telmisartan/HCT Sandoz [SZ] | [a] Mizart HCT 80/12.5 mg [AF]<br>[a] Teltartan HCT 80/12.5 [RW] |
| | | [B]8.02 | *29.61 | 22.99 | [a] Micardis Plus 80/12.5 mg [BY] | |

**telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28**

13607E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *22.25 | 23.65 | [a] APO-Telmisartan HCTZ 80/25 [TX]<br>[a] Telmisartan HCT GH 80/25 [GQ]<br>[a] Teltartan HCT 80/25 [RW] | [a] Mizart HCT 80/25 mg [AF]<br>[a] Telmisartan/HCT Sandoz [SZ] |
| | | [B]7.94 | *30.19 | 23.65 | [a] Micardis Plus 80/25 mg [BY] | |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9373H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.24 | 22.64 | [a] Co-Diovan 160/12.5 [NV] | [a] Dilart HCT 160/12.5 [AF] |

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

9374J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 22.34 | 23.74 | [a] Co-Diovan 160/25 [NV] | [a] Dilart HCT 160/25 [AF] |

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9372G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.66 | 21.06 | [a] Co-Diovan 80/12.5 [NV] | [a] Dilart HCT 80/12.5 [AF] |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13606D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *29.49 | 30.00 | [a] Co-Diovan 160/12.5 [NV] | [a] Dilart HCT 160/12.5 [AF] |

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13453C NP | 2 | 5 | .. | *31.69 | 30.00 | [a] Co-Diovan 160/25 [NV] | [a] Dilart HCT 160/25 [AF] |

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13393X NP | 2 | 5 | .. | *26.33 | 27.73 | [a] Co-Diovan 80/12.5 [NV] | [a] Dilart HCT 80/12.5 [AF] |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9481B NP | 1 | 5 | .. | 23.26 | 24.66 | [a] Co-Diovan 320/12.5 [NV] | [a] Dilart HCT 320/12.5 [AF] |

**valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9482C NP | 1 | 5 | .. | 24.35 | 25.75 | [a] Co-Diovan 320/25 [NV] | [a] Dilart HCT 320/25 [AF] |

## ▪ VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13517K NP | 2 | 5 | .. | *33.53 | 30.00 | [a] Co-Diovan 320/12.5 [NV] | [a] Dilart HCT 320/12.5 [AF] |

**valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13455E NP | 2 | 5 | .. | *35.71 | 30.00 | [a] Co-Diovan 320/25 [NV] | [a] Dilart HCT 320/25 [AF] |

*Angiotensin II receptor blockers (ARBs) and calcium channel blockers*

## ▪ AMLODIPINE + VALSARTAN

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9377M NP | 1 | 5 | .. | 23.53 | 24.93 | [a] Valsartan/Amlodipine Novartis 160/10 [NM] |
| | | | [B]4.00 | 27.53 | 24.93 | [a] Exforge 10/160 [NV] |

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5460J NP | 1 | 5 | .. | 25.80 | 27.20 | [a] Valsartan/Amlodipine Novartis 320/10 [NM] |
| | | | [B]4.00 | 29.80 | 27.20 | [a] Exforge 10/320 [NV] |

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9376L NP | 1 | 5 | .. | 23.00 | 24.40 | [a] Valsartan/Amlodipine Novartis 160/5 [NM] |
| | | | [B]4.00 | 27.00 | 24.40 | [a] Exforge 5/160 [NV] |

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5459H NP | 1 | 5 | .. | 25.59 | 26.99 | [a] Valsartan/Amlodipine Novartis 320/5 [NM] |
| | | | [B]4.00 | 29.59 | 26.99 | [a] Exforge 5/320 [NV] |

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9375K NP | 1 | 5 | .. | 20.97 | 22.37 | [a] Valsartan/Amlodipine Novartis 80/5 [NM] |
| | | | [B]4.00 | 24.97 | 22.37 | [a] Exforge 5/80 [NV] |

## ▪ AMLODIPINE + VALSARTAN

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13454D NP | 2 | 5 | .. | *34.07 | 30.00 | [a] Valsartan/Amlodipine Novartis 160/10 [NM] |
| | | | [B]8.00 | *42.07 | 30.00 | [a] Exforge 10/160 [NV] |

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13389Q NP | 2 | 5 | .. | *38.61 | 30.00 | [a] Valsartan/Amlodipine Novartis 320/10 [NM] |
| | | | [B]8.00 | *46.61 | 30.00 | [a] Exforge 10/320 [NV] |

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13516J NP | 2 | 5 | .. | *33.01 | 30.00 | [a] Valsartan/Amlodipine Novartis 160/5 [NM] |
| | | | [B]8.00 | *41.01 | 30.00 | [a] Exforge 5/160 [NV] |

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13604B NP | 2 | 5 | .. | *38.19 | 30.00 | [a] Valsartan/Amlodipine Novartis 320/5 [NM] |
| | | | [B]8.00 | *46.19 | 30.00 | [a] Exforge 5/320 [NV] |

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13421J NP | 2 | 5 | .. | *28.95 | 30.00 | [a] Valsartan/Amlodipine Novartis 80/5 [NM] |
| | | | [B]8.00 | *36.95 | 30.00 | [a] Exforge 5/80 [NV] |

## ▪ OLMESARTAN + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5292M NP | 1 | 5 | .. | 16.88 | 18.28 | [a] OLMEKAR [RW] | [a] Olmesartan/Amlodipine 20/5 APOTEX [TX] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 20/5 [AF] | [a] Pharmacor Olmesartan Amlodipine 20/5 [CR] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Sevikar 20/5 [AL] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

| 5294P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.01 | 22.41 | [a] OLMEKAR [RW] | [a] Olmesartan/Amlodipine 40/10 APOTEX [TX] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/10 [AF] | [a] Pharmacor Olmesartan Amlodipine 40/10 [CR] |
| | | | [B]3.00 | 24.01 | 22.41 | [a] Sevikar 40/10 [AL] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30**

| 5293N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.47 | 21.87 | [a] OLMEKAR [RW] | [a] Olmesartan/Amlodipine 40/5 APOTEX [TX] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/5 [AF] | [a] Pharmacor Olmesartan Amlodipine 40/5 [CR] |
| | | | [B]3.00 | 23.47 | 21.87 | [a] Sevikar 40/5 [AL] | |

## ▪ OLMESARTAN + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

| 13449W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.77 | 22.17 | [a] OLMEKAR [RW] | [a] Olmesartan/Amlodipine 20/5 APOTEX [TX] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 20/5 [AF] | [a] Pharmacor Olmesartan Amlodipine 20/5 [CR] |
| | | | | | | [a] Sevikar 20/5 [AL] | |

## ▪ TELMISARTAN + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

| 8979N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] Pritor/Amlodipine [FI] |
| | | | [B]5.49 | 22.24 | 18.15 | [a] Twynsta [BY] |

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

| 8978M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.13 | 17.53 | [a] Pritor/Amlodipine [FI] |
| | | | [B]5.53 | 21.66 | 17.53 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

| 8981Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.60 | 21.00 | [a] Pritor/Amlodipine [FI] |
| | | | [B]5.30 | 24.90 | 21.00 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

| 8980P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.96 | 20.36 | [a] Pritor/Amlodipine [FI] |
| | | | [B]5.30 | 24.26 | 20.36 | [a] Twynsta [BY] |

## ▪ TELMISARTAN + AMLODIPINE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR

- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13515H NP | 2 | 5 | .. | *20.51 | 21.91 | [a] Pritor/Amlodipine [FI] |
| | | | [B]10.98 | *31.49 | 21.91 | [a] Twynsta [BY] |

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13483P NP | 2 | 5 | .. | *19.27 | 20.67 | [a] Pritor/Amlodipine [FI] |
| | | | [B]11.06 | *30.33 | 20.67 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13451Y NP | 2 | 5 | .. | *26.21 | 27.61 | [a] Pritor/Amlodipine [FI] |
| | | | [B]10.60 | *36.81 | 27.61 | [a] Twynsta [BY] |

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13450X NP | 2 | 5 | .. | *24.93 | 26.33 | [a] Pritor/Amlodipine [FI] |
| | | | [B]10.60 | *35.53 | 26.33 | [a] Twynsta [BY] |

*Angiotensin II receptor blockers (ARBs), other combinations*

## ▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5287G NP | 1 | 5 | .. | 25.04 | 26.44 | [a] Valsartan/Amlodipine/HCT Novartis 160/10/12.5 [NM] |
| | | | [B]4.00 | 29.04 | 26.44 | [a] Exforge HCT 10/160/12.5 [NV] |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5288H NP | 1 | 5 | .. | 26.56 | 27.96 | [a] Valsartan/Amlodipine/HCT Novartis 160/10/25 [NM] |
| | | | [B]10.00 | 36.56 | 27.96 | [a] Exforge HCT 10/160/25 [NV] |

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5289J NP | 1 | 5 | .. | 28.83 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 320/10/25 [NM] |
| | | | [B]4.00 | 32.83 | 30.00 | [a] Exforge HCT 10/320/25 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5285E NP | 1 | 5 | .. | 24.52 | 25.92 | [a] Valsartan/Amlodipine/HCT Novartis 160/5/12.5 [NM] |
| | | | [B]10.00 | 34.52 | 25.92 | [a] Exforge HCT 5/160/12.5 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5286F NP | 1 | 5 | .. | 26.03 | 27.43 | [a] Valsartan/Amlodipine/HCT Novartis 160/5/25 [NM] |
| | | | [B]4.00 | 30.03 | 27.43 | [a] Exforge HCT 5/160/25 [NV] |

## ▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13514G NP | 2 | 5 | .. | *37.09 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 160/10/12.5 [NM] |
| | | | [B]8.00 | *45.09 | 30.00 | [a] Exforge HCT 10/160/12.5 [NV] |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13390R NP | 2 | 5 | .. | *40.13 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 160/10/25 [NM] |
| | | | [B]20.00 | *60.13 | 30.00 | [a] Exforge HCT 10/160/25 [NV] |

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13573J NP | 2 | 5 | .. | *44.67 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 320/10/25 [NM] |
| | | | [B]8.00 | *52.67 | 30.00 | [a] Exforge HCT 10/320/25 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13448T NP | 2 | 5 | .. | *36.05 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 160/5/12.5 [NM] |
| | | | [B]20.00 | *56.05 | 30.00 | [a] Exforge HCT 5/160/12.5 [NV] |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13603Y NP | 2 | 5 | .. | *39.07 | 30.00 | [a] Valsartan/Amlodipine/HCT Novartis 160/5/25 [NM] |
| | | | [B]8.00 | *47.07 | 30.00 | [a] Exforge HCT 5/160/25 [NV] |

## ▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10005N NP | 1 | 5 | .. | 18.98 | 20.38 | [a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]<br>[a] Olmekar HCT 20/5/12.5 [RF] | [a] Olamlo HCT 20/5/12.5 [AL] |
| | | | [B]3.00 | 21.98 | 20.38 | [a] Sevikar HCT 20/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2880N NP | 1 | 5 | .. | 23.06 | 24.46 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX]<br>[a] Olmekar HCT 40/5/12.5 [RF] | [a] Olamlo HCT 40/5/12.5 [AL] |
| | | | [B]3.00 | 26.06 | 24.46 | [a] Sevikar HCT 40/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2836G NP | 1 | 5 | .. | 23.54 | 24.94 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX]<br>[a] Olmekar HCT 40/10/12.5 [RF] | [a] Olamlo HCT 40/10/12.5 [AL] |
| | | | [B]2.95 | 26.49 | 24.94 | [a] Sevikar HCT 40/10/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2864R NP | 1 | 5 | .. | 24.63 | 26.03 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX]<br>[a] Olmekar HCT 40/5/25 [RF] | [a] Olamlo HCT 40/5/25 [AL] |
| | | | [B]3.00 | 27.63 | 26.03 | [a] Sevikar HCT 40/5/25 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2953K NP | 1 | 5 | .. | 25.10 | 26.50 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]<br>[a] Olmekar HCT 40/10/25 [RF] | [a] Olamlo HCT 40/10/25 [AL] |
| | | | [B]3.00 | 28.10 | 26.50 | [a] Sevikar HCT 40/10/25 [AF] | |

## ▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13481M NP | 2 | 5 | .. | *24.97 | 26.37 | [a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]<br>[a] Olmekar HCT 20/5/12.5 [RF] | [a] Olamlo HCT 20/5/12.5 [AL] |
| | | | [B]6.00 | *30.97 | 26.37 | [a] Sevikar HCT 20/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13513F NP | 2 | 5 | .. | *33.13 | 30.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX]<br>[a] Olmekar HCT 40/5/12.5 [RF] | [a] Olamlo HCT 40/5/12.5 [AL] |
| | | | [B]6.00 | *39.13 | 30.00 | [a] Sevikar HCT 40/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13482N NP | 2 | 5 | .. | *34.09 | 30.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX]<br>[a] Olmekar HCT 40/10/12.5 [RF] | [a] Olamlo HCT 40/10/12.5 [AL] |
| | | | [B]5.90 | *39.99 | 30.00 | [a] Sevikar HCT 40/10/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13512E NP | 2 | 5 | .. | *36.27 | 30.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX]<br>[a] Olmekar HCT 40/5/25 [RF] | [a] Olamlo HCT 40/5/25 [AL] |
| | | | [B]6.00 | *42.27 | 30.00 | [a] Sevikar HCT 40/5/25 [AF] | |

## ▪ SACUBITRIL + VALSARTAN

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

**Note** Continuing therapy by a nurse practitioner may include dose titrations/changes, but only after therapy was initiated by a medical practitioner.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***11680***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment**,** which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR

- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11123K NP | 1 | 5 | .. | 192.10 | 30.00 | Entresto [NV] |

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11131W NP | 1 | 5 | .. | 192.10 | 30.00 | Entresto [NV] |

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11122J NP | 1 | 5 | .. | 192.10 | 30.00 | Entresto [NV] |

## ▪ SACUBITRIL + VALSARTAN

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

**Note** Continuing therapy by a nurse practitioner may include dose titrations/changes, but only after therapy was initiated by a medical practitioner.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14254***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment**,** which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13570F NP | 2 | 5 | .. | *376.21 | 30.00 | Entresto [NV] |

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13511D NP | 2 | 5 | .. | *376.21 | 30.00 | Entresto [NV] |

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13445P NP | 2 | 5 | .. | *376.21 | 30.00 | Entresto [NV] |

# ▪ LIPID MODIFYING AGENTS

## LIPID MODIFYING AGENTS, PLAIN

*HMG CoA reductase inhibitors*

## ▪ ATORVASTATIN

**atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8213G NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Atorvastatin [TX]<br>[a] Atorvastatin GH [GQ]<br>[a] Blooms the Chemist Atorvastatin [IB]<br>[a] Lorstat 10 [AF] | [a] Atorvachol [RF]<br>[a] Atorvastatin SZ [HX]<br>[a] Lipitor [AS]<br>[a] NOUMED ATORVASTATIN [VO] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 20 mg tablet, 30**

| 8214H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.80 | 17.20 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 20 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 40 mg tablet, 30**

| 8215J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.70 | 18.10 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 40 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 80 mg tablet, 30**

| 8521L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.29 | 18.69 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 80 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

## ▪ ATORVASTATIN

**Restricted benefit**

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

**atorvastatin 10 mg tablet, 30**

| 13495G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 10 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 20 mg tablet, 30**

| 13529C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.61 | 20.01 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 20 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 40 mg tablet, 30**

| 13468W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.41 | 21.81 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |
| | | | | | | [a] Lorstat 40 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 80 mg tablet, 30**

| 13374X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Atorvastatin [TX] | [a] Atorvachol [RF] |
| | | | | | | [a] Atorvastatin GH [GQ] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] Blooms the Chemist Atorvastatin [IB] | [a] Lipitor [AS] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Lorstat 80 [AF] | [a] NOUMED ATORVASTATIN [VO] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

## ▪ FLUVASTATIN

### fluvastatin 80 mg modified release tablet, 28

2863Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 36.62 | 30.00 | Lescol XL [NV] |

NP

## ▪ FLUVASTATIN

**Restricted benefit**

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

### fluvastatin 80 mg modified release tablet, 28

13558N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *60.25 | 30.00 | Lescol XL [NV] |

NP

## ▪ PRAVASTATIN

### pravastatin sodium 10 mg tablet, 30

2833D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Lipostat 10 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | [B]2.93 | 18.63 | 17.10 | [a] Cholstat 10 [AF] | |
| | | [B]4.95 | 20.65 | 17.10 | [a] Pravachol [RW] | |

NP

### pravastatin sodium 20 mg tablet, 30

2834E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.97 | 17.37 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Cholstat 20 [AF] | [a] Lipostat 20 [RF] |
| | | | | | [a] Pravastatin Sandoz [SZ] | |
| | | [B]4.98 | 20.95 | 17.37 | [a] Pravachol [RW] | |

NP

### pravastatin sodium 40 mg tablet, 30

8197K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.79 | 18.19 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Cholstat 40 [AF] | [a] Lipostat 40 [RF] |
| | | | | | [a] Pravastatin Sandoz [SZ] | |
| | | [B]4.98 | 21.77 | 18.19 | [a] Pravachol [RW] | |

NP

### pravastatin sodium 80 mg tablet, 30

8829Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.83 | 20.23 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Lipostat 80 [RF] | |
| | | [B]5.15 | 23.98 | 20.23 | [a] Pravachol [RW] | |

NP

## ▪ PRAVASTATIN

**Restricted benefit**

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

### pravastatin sodium 10 mg tablet, 30

13496H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Lipostat 10 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | [B]5.86 | *24.27 | 19.81 | [a] Cholstat 10 [AF] | |
| | | [B]9.90 | *28.31 | 19.81 | [a] Pravachol [RW] | |

NP

### pravastatin sodium 20 mg tablet, 30

13497J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.95 | 20.35 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Cholstat 20 [AF] | [a] Lipostat 20 [RF] |
| | | | | | [a] Pravastatin Sandoz [SZ] | |
| | | [B]9.96 | *28.91 | 20.35 | [a] Pravachol [RW] | |

NP

### pravastatin sodium 40 mg tablet, 30

13432Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.59 | 21.99 | [a] APO-Pravastatin [TX] | [a] APX-Pravastatin [TY] |
| | | | | | [a] Cholstat 40 [AF] | [a] Lipostat 40 [RF] |
| | | | | | [a] Pravastatin Sandoz [SZ] | |
| | | [B]9.96 | *30.55 | 21.99 | [a] Pravachol [RW] | |

NP

**pravastatin sodium 80 mg tablet, 30**

| 13527Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *24.67 | 26.07 | [a] APO-Pravastatin [TX]<br>[a] Lipostat 80 [RF] | [a] APX-Pravastatin [TY] |
| | | | [B]10.30 | *34.97 | 26.07 | [a] Pravachol [RW] | |

## ▪ ROSUVASTATIN

**rosuvastatin 10 mg tablet, 30**

| 2628H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APX-Rosuvastatin [TY]<br>[a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Crosuva 10 [RW]<br>[a] Pharmacor Rosuvastatin 10 [CR]<br>[a] Rosuvastatin Lupin [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms Rosuvastatin [BG]<br>[a] Cavstat [AF]<br>[a] Noumed Rosuvastatin [VO]<br>[a] Rosuvastatin APOTEX [GX]<br>[a] Rosuvastatin RBX [RA] |
| | | | [B]3.63 | 20.38 | 18.15 | [a] Crestor [FK] | |

**rosuvastatin 20 mg tablet, 30**

| 2574L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.81 | 18.21 | [a] APX-Rosuvastatin [TY]<br>[a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Crosuva 20 [RW]<br>[a] Pharmacor Rosuvastatin 20 [CR]<br>[a] Rosuvastatin Lupin [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms Rosuvastatin [BG]<br>[a] Cavstat [AF]<br>[a] Noumed Rosuvastatin [VO]<br>[a] Rosuvastatin APOTEX [GX]<br>[a] Rosuvastatin RBX [RA] |
| | | | [B]3.59 | 20.40 | 18.21 | [a] Crestor [FK] | |

**rosuvastatin 40 mg tablet, 30**

| 2594M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 18.43 | 19.83 | [a] APX-Rosuvastatin [TY]<br>[a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Crosuva 40 [RW]<br>[a] Pharmacor Rosuvastatin 40 [CR]<br>[a] Rosuvastatin Lupin [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms Rosuvastatin [BG]<br>[a] Cavstat [AF]<br>[a] Noumed Rosuvastatin [VO]<br>[a] Rosuvastatin APOTEX [GX]<br>[a] Rosuvastatin RBX [RA] |
| | | | [B]4.41 | 22.84 | 19.83 | [a] Crestor [FK] | |

**rosuvastatin 5 mg tablet, 30**

| 2606E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APX-Rosuvastatin [TY]<br>[a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Crosuva 5 [RW]<br>[a] Pharmacor Rosuvastatin 5 [CR]<br>[a] Rosuvastatin Lupin [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms Rosuvastatin [BG]<br>[a] Cavstat [AF]<br>[a] Noumed Rosuvastatin [VO]<br>[a] Rosuvastatin APOTEX [GX]<br>[a] Rosuvastatin RBX [RA] |
| | | | [B]3.70 | 19.40 | 17.10 | [a] Crestor [FK] | |

## ▪ ROSUVASTATIN

**Restricted benefit**

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

**rosuvastatin 10 mg tablet, 30**

| 13586C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APX-Rosuvastatin [TY]<br>[a] Blooms the Chemist Rosuvastatin [IB]<br>[a] Crosuva 10 [RW]<br>[a] Pharmacor Rosuvastatin 10 [CR]<br>[a] Rosuvastatin Lupin [GQ]<br>[a] Rosuvastatin Sandoz [SZ] | [a] Blooms Rosuvastatin [BG]<br>[a] Cavstat [AF]<br>[a] Noumed Rosuvastatin [VO]<br>[a] Rosuvastatin APOTEX [GX]<br>[a] Rosuvastatin RBX [RA] |
| | | | [B]7.26 | *27.77 | 21.91 | [a] Crestor [FK] | |

**rosuvastatin 20 mg tablet, 30**

| 13588E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.63 | 22.03 | [a] APX-Rosuvastatin [TY] | [a] Blooms Rosuvastatin [BG] |
| | | | | | | [a] Blooms the Chemist Rosuvastatin [IB] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 20 [RW] | [a] Noumed Rosuvastatin [VO] |
| | | | | | | [a] Pharmacor Rosuvastatin 20 [CR] | [a] Rosuvastatin APOTEX [GX] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | |
| | | | [B]7.18 | *27.81 | 22.03 | [a] Crestor [FK] | |

**rosuvastatin 40 mg tablet, 30**

| 13589F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *23.87 | 25.27 | [a] APX-Rosuvastatin [TY] | [a] Blooms Rosuvastatin [BG] |
| | | | | | | [a] Blooms the Chemist Rosuvastatin [IB] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 40 [RW] | [a] Noumed Rosuvastatin [VO] |
| | | | | | | [a] Pharmacor Rosuvastatin 40 [CR] | [a] Rosuvastatin APOTEX [GX] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | |
| | | | [B]8.82 | *32.69 | 25.27 | [a] Crestor [FK] | |

**rosuvastatin 5 mg tablet, 30**

| 13406N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] APX-Rosuvastatin [TY] | [a] Blooms Rosuvastatin [BG] |
| | | | | | | [a] Blooms the Chemist Rosuvastatin [IB] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 5 [RW] | [a] Noumed Rosuvastatin [VO] |
| | | | | | | [a] Pharmacor Rosuvastatin 5 [CR] | [a] Rosuvastatin APOTEX [GX] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | |
| | | | [B]7.40 | *25.81 | 19.81 | [a] Crestor [FK] | |

## ▪ SIMVASTATIN

**simvastatin 10 mg tablet, 30**

| 2011W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Simvastatin [TX] | [a] NOUMED SIMVASTATIN [VO] |
| | | | | | | [a] Simvar 10 [RW] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Zimstat [AF] | |

**simvastatin 20 mg tablet, 30**

| 2012X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] APO-Simvastatin [TX] | [a] NOUMED SIMVASTATIN [VO] |
| | | | | | | [a] Simvar 20 [RW] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]9.28 | 24.98 | 17.10 | [a] Lipex 20 [AL] | [a] Zocor [MQ] |

**simvastatin 40 mg tablet, 30**

| 8173E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.87 | 17.27 | [a] APO-Simvastatin [TX] | [a] NOUMED SIMVASTATIN [VO] |
| | | | | | | [a] Simvar 40 [RW] | [a] Simvastatin Sandoz [SZ] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]9.24 | 25.11 | 17.27 | [a] Lipex 40 [AL] | [a] Zocor [MQ] |

**simvastatin 5 mg tablet, 30**

| 2013Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.70 | 17.10 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 80 mg tablet, 30**

| 8313M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.75 | 18.15 | [a] APO-Simvastatin [TX] | [a] Simvar 80 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

## ▪ SIMVASTATIN

**Restricted benefit**

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

**simvastatin 10 mg tablet, 30**

| 13528B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Simvastatin [TX]<br>[a] Simvar 10 [RW]<br>[a] Zimstat [AF] | [a] NOUMED SIMVASTATIN [VO]<br>[a] Simvastatin Sandoz [SZ] |

**simvastatin 20 mg tablet, 30**

| 13373W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Simvastatin [TX]<br>[a] Simvar 20 [RW]<br>[a] Zimstat [AF] | [a] NOUMED SIMVASTATIN [VO]<br>[a] Simvastatin Sandoz [SZ] |
| | | | [B]18.56 | *36.97 | 19.81 | [a] Lipex 20 [AL] | [a] Zocor [MQ] |

**simvastatin 40 mg tablet, 30**

| 13471B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.75 | 20.15 | [a] APO-Simvastatin [TX]<br>[a] Simvar 40 [RW]<br>[a] Zimstat [AF] | [a] NOUMED SIMVASTATIN [VO]<br>[a] Simvastatin Sandoz [SZ] |
| | | | [B]18.48 | *37.23 | 20.15 | [a] Lipex 40 [AL] | [a] Zocor [MQ] |

**simvastatin 5 mg tablet, 30**

| 13559P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 80 mg tablet, 30**

| 13498K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APO-Simvastatin [TX]<br>[a] Simvastatin Sandoz [SZ] | [a] Simvar 80 [RW]<br>[a] Zimstat [AF] |

*Fibrates*

## ▪ FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**fenofibrate 145 mg tablet, 30**

| 9023X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 22.11 | 23.51 | [a] APO-Fenofibrate [TX]<br>[a] Fenocol [YC]<br>[a] Fenofibrate Mylan [AF]<br>[a] Fenofibrate Sandoz [SZ]<br>[a] Lipidil [GO] | [a] Blooms the Chemist Fenofibrate [IB]<br>[a] Fenofibrate Cipla [LR]<br>[a] FENOFIBRATE RBX [RA]<br>[a] Fenofibrate Viatris [AL] |

**fenofibrate 48 mg tablet, 60**

| 9022W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.08 | 20.48 | [a] APO-Fenofibrate [TX]<br>[a] Fenofibrate Mylan [AF]<br>[a] Fenofibrate Viatris [AL] | [a] Fenofibrate Cipla [LR]<br>[a] FENOFIBRATE RBX [RA]<br>[a] Lipidil [GO] |

## ▪ FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

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

**fenofibrate 145 mg tablet, 30**

| 13587D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *31.23 | 30.00 | [a] APO-Fenofibrate [TX]<br>[a] Fenocol [YC]<br>[a] FENOFIBRATE RBX [RA]<br>[a] Fenofibrate Viatris [AL] | [a] Blooms the Chemist Fenofibrate [IB]<br>[a] Fenofibrate Cipla [LR]<br>[a] Fenofibrate Sandoz [SZ]<br>[a] Lipidil [GO] |

**fenofibrate 48 mg tablet, 60**

| 13469X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *25.17 | 26.57 | [a] APO-Fenofibrate [TX]<br>[a] FENOFIBRATE RBX [RA] | [a] Fenofibrate Cipla [LR]<br>[a] Fenofibrate Viatris [AL] |

[a] Lipidil [GO]

## ▪ GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**gemfibrozil 600 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1453L NP | 1 | 5 | .. | 22.89 | 24.29 | [a] Ausgem [RW] | [a] Lipigem [AF] |

## ▪ GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

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

**gemfibrozil 600 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13618R NP | 2 | 5 | .. | *32.79 | 30.00 | [a] Ausgem [RW] | [a] Lipigem [AF] |

*Bile acid sequestrants*

## ▪ COLESTYRAMINE

**colestyramine 4 g powder for oral liquid, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13351Q NP | 3.33 | 5 | .. | *222.43 | 30.00 | JAMP-Cholestyramine [DZ] |

**colestyramine 4 g powder for oral liquid, 50 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2967E NP | 2 | 5 | .. | *82.41 | 30.00 | Questran Lite [GO] |

## ▪ COLESTYRAMINE

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

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

**Restricted benefit**

Primary hypercholesterolaemia

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**colestyramine 4 g powder for oral liquid, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13347L | 3.33 | 11 | .. | *222.43 | 30.00 | JAMP-Cholestyramine [DZ] |

**colestyramine 4 g powder for oral liquid, 50 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9249T | 2 | 11 | .. | *82.41 | 30.00 | Questran Lite [GO] |

*Other lipid modifying agents*

## ▪ ALIROCUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12010***

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**

- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug.

**Authority required (STREAMLINED)**

***12011***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.

**alirocumab 150 mg/mL injection, 2 x 1 mL pen devices**

12608N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 499.16 | 30.00 | Praluent [SW] |

**alirocumab 75 mg/mL injection, 2 x 1 mL pen devices**

12607M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 499.16 | 30.00 | Praluent [SW] |

## ▪ ALIROCUMAB

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

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

**Note** Special Pricing Arrangements apply.

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

**Authority required**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

**Authority required**

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre prior to commencing treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise.

**Treatment criteria:**

- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years of more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

**alirocumab 150 mg/mL injection, 2 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12604J | 1 | 5 | .. | 499.16 | 30.00 | Praluent [SW] |

**alirocumab 75 mg/mL injection, 2 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12613W | 1 | 5 | .. | 499.16 | 30.00 | Praluent [SW] |

## ▪ EVOLOCUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10388***

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11972D | 1 | 5 | .. | 366.21 | 30.00 | Repatha [AN] |

**evolocumab 140 mg/mL injection, 1 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11977J | 3 | 5 | .. | *504.18 | 30.00 | Repatha [AN] |

## ▪ EVOLOCUMAB

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

**Note** Special Pricing Arrangements apply.

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

**Authority required**

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information

**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

11193D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 366.21 | 30.00 | Repatha [AN] |

**evolocumab 140 mg/mL injection, 1 mL pen device**

10958R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *504.18 | 30.00 | Repatha [AN] |

## ▪ EVOLOCUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12010***

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug.

**Authority required (STREAMLINED)**

***12011***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from another drug within the same pharmacological class

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR

- Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.

**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

11986W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 366.21 | 30.00 | Repatha [AN] |

**evolocumab 140 mg/mL injection, 1 mL pen device**

11985T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *338.79 | 30.00 | Repatha [AN] |

## ▪ EVOLOCUMAB

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

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

**Note** Special Pricing Arrangements apply.

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

**Authority required**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout

period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

**Authority required**

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless

there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years of more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

**Authority required**

Non-familial hypercholesterolaemia

Treatment Phase: Grandfather treatment

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years of more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Authority required**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Grandfather treatment

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a specialist physician; OR

- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved.

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

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

11485L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 366.21 | 30.00 | Repatha [AN] |

**evolocumab 140 mg/mL injection, 1 mL pen device**

11484K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *338.79 | 30.00 | Repatha [AN] |

## ▪ EZETIMIBE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***7996***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR

- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***7966***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***7990***

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous sitosterolaemia.

### ezetimibe 10 mg tablet, 30

8757X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.89 | 23.29 | [a] APO-Ezetimibe [TX] | [a] Blooms The Chemist Ezetimibe [IB] |
| | | | | | [a] BTC Ezetimibe [BG] | [a] EZEMICHOL [RW] |
| | | | | | [a] Ezetimibe GH [GQ] | [a] Ezetimibe Sandoz [SZ] |
| | | | | | [a] Pharmacor Ezetimibe 10 [CR] | [a] Zient 10mg [AF] |
| | | [B]3.40 | 25.29 | 23.29 | [a] Ezetrol [AL] | |

## ▪ EZETIMIBE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***14249***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***14283***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***14310***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have homozygous sitosterolaemia.

**ezetimibe 10 mg tablet, 30**

13440J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *30.79 | 30.00 | [a] APO-Ezetimibe [TX] | [a] Blooms The Chemist Ezetimibe [IB] |
| | | | | | [a] BTC Ezetimibe [BG] | [a] EZEMICHOL [RW] |
| | | | | | [a] Ezetimibe GH [GQ] | [a] Ezetimibe Sandoz [SZ] |
| | | | | | [a] Pharmacor Ezetimibe 10 [CR] | [a] Zient 10mg [AF] |
| | | [B]6.80 | *37.59 | 30.00 | [a] Ezetrol [AL] | |

## LIPID MODIFYING AGENTS, COMBINATIONS

*Combinations of various lipid modifying agents*

### ▪ EZETIMIBE (&) ROSUVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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**Authority required (STREAMLINED)**

***7957***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

10208G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 24.63 | 26.03 | [a] Ezalo Composite Pack 10mg+10mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]4.00 | 28.63 | 26.03 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

10201X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP ‡1 | 5 | .. | 24.38 | 25.78 | [a] Ezalo Composite Pack 10mg+20mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |
| | | [B]4.00 | 28.38 | 25.78 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

10207F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP ‡1 | 5 | .. | 25.43 | 26.83 | [a] Ezalo Composite Pack 10mg+40mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |
| | | [B]4.00 | 29.43 | 26.83 | [a] Rosuzet Composite Pack [AL] | |

## ▪ EZETIMIBE (&) ROSUVASTATIN

**Note Continuing Therapy Only:**

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

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***7958***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

10204C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP ‡1 | 5 | .. | 23.09 | 24.49 | [a] Ezalo Composite Pack 10mg+5mg [AF] |
| | | [B]4.00 | 27.09 | 24.49 | [a] Rosuzet Composite Pack [AL] |

## ▪ EZETIMIBE (&) ROSUVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***14284***
Hypercholesterolaemia
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

13569E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | .. | *36.27 | 30.00 | [a] Ezalo Composite Pack 10mg+10mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |
| | | [B]8.00 | *44.27 | 30.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

13480L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | .. | *35.77 | 30.00 | [a] Ezalo Composite Pack 10mg+20mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |
| | | [B]8.00 | *43.77 | 30.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

13537L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | .. | *37.87 | 30.00 | [a] Ezalo Composite Pack 10mg+40mg [AF] | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] |
| | | [B]8.00 | *45.87 | 30.00 | [a] Rosuzet Composite Pack [AL] | |

## ▪ EZETIMIBE (&) ROSUVASTATIN

**Note Continuing Therapy Only:**
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**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**
***14350***
Hypercholesterolaemia
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR

- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

13629H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | .. | *33.19 | 30.00 | [a] Ezalo Composite Pack 10mg+5mg [AF] |
| | | [B]8.00 | *41.19 | 30.00 | [a] Rosuzet Composite Pack [AL] |

## ▪ EZETIMIBE + ATORVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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**Authority required (STREAMLINED)**

***7957***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

| 10393B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.15 | 25.55 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/20 [GQ] |
| | | | [B]3.00 | 27.15 | 25.55 | [a] Atozet [AF] | |

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

| 10377E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 25.06 | 26.46 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/40 [GQ] |
| | | | [B]3.00 | 28.06 | 26.46 | [a] Atozet [AF] | |

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

| 10376D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.19 | 27.59 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/80 [GQ] |
| | | | [B]2.95 | 29.14 | 27.59 | [a] Atozet [AF] | |

## ▪ EZETIMIBE + ATORVASTATIN

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**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***7958***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

| 10392Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.42 | 24.82 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/10 [GQ] |
| | | | [B]3.00 | 26.42 | 24.82 | [a] Atozet [AF] | |

## ▪ EZETIMIBE + ATORVASTATIN

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**Note Continuing Therapy Only:**

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patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***14284***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

13416D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *37.13 | 30.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/40 [GQ] |
| | | [B]6.00 | *43.13 | 30.00 | [a] Atozet [AF] | |

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

13538M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *39.39 | 30.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/80 [GQ] |
| | | [B]5.90 | *45.29 | 30.00 | [a] Atozet [AF] | |

## ▪ EZETIMIBE + ATORVASTATIN

**Note Continuing Therapy Only:**

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

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***14269***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR

- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

13539N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *33.85 | 30.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/10 [GQ] |
| | | [B]6.00 | *39.85 | 30.00 | [a] Atozet [AF] | |

## ▪ EZETIMIBE + ATORVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***14348***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

13622Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *35.31 | 30.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/20 [GQ] |
| | | [B]6.00 | *41.31 | 30.00 | [a] Atozet [AF] | |

## ▪ EZETIMIBE + SIMVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***7957***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

8881K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 24.23 | 25.63 | [a] APO-Ezetimibe/Simvastatin 10/40 [TX] | [a] EZESIM 10/40 [RZ] |
| | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | [a] EZEVYT 10/40 [LR] | [a] EzSimva GH 10/40 [GQ] |
| | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/40 [CR] | [a] Vytorin [AL] |
| | | | | | [a] Zeklen 10/40 mg [AF] | |

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

8882L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.23 | 26.63 | [a] APO-Ezetimibe/Simvastatin 10/80 [TX] | [a] EZESIM 10/80 [RZ] |
| | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | [a] EZEVYT 10/80 [LR] | [a] EzSimva GH 10/80 [GQ] |
| | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/80 [CR] | [a] Vytorin [AL] |
| | | | | | [a] Zeklen 10/80 mg [AF] | |

## ▪ EZETIMIBE + SIMVASTATIN

**Note Continuing Therapy Only:**

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

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***7958***

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**

- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

| 9483D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.01 | 24.41 | [a] APO-Ezetimibe/Simvastatin 10/10 [TX] | [a] EZESIM 10/10 [RZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | | [a] EZEVYT 10/10 [LR] | [a] EzSimva GH 10/10 [GQ] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/10 [CR] | [a] Vytorin [AL] |
| | | | | | | [a] Zeklen 10/10 mg [AF] | |

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

| 9484E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 23.52 | 24.92 | [a] APO-Ezetimibe/Simvastatin 10/20 [TX] | [a] EZESIM 10/20 [RZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | | [a] EZEVYT 10/20 [LR] | [a] EzSimva GH 10/20 [GQ] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/20 [CR] | [a] Vytorin [AL] |
| | | | | | | [a] Zeklen 10/20 mg [AF] | |

## ▪ EZETIMIBE + SIMVASTATIN

**Note Continuing Therapy Only:**

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**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Authority required (STREAMLINED)**

***14269***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR

- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

13385L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *33.03 | 30.00 | [a] APO-Ezetimibe/Simvastatin 10/10 [TX] | [a] EZESIM 10/10 [RZ] |
| | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | [a] EZEVYT 10/10 [LR] | [a] EzSimva GH 10/10 [GQ] |
| | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/10 [CR] | [a] Vytorin [AL] |
| | | | | | [a] Zeklen 10/10 mg [AF] | |

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

13442L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *34.05 | 30.00 | [a] APO-Ezetimibe/Simvastatin 10/20 [TX] | [a] EZESIM 10/20 [RZ] |
| | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | [a] EZEVYT 10/20 [LR] | [a] EzSimva GH 10/20 [GQ] |
| | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/20 [CR] | [a] Vytorin [AL] |
| | | | | | [a] Zeklen 10/20 mg [AF] | |

## ▪ EZETIMIBE + SIMVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***14284***

Hypercholesterolaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR

- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

| 13535J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *35.47 | 30.00 | [a] APO-Ezetimibe/Simvastatin 10/40 [TX] | [a] EZESIM 10/40 [RZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | | [a] EZEVYT 10/40 [LR] | [a] EzSimva GH 10/40 [GQ] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/40 [CR] | [a] Vytorin [AL] |
| | | | | | | [a] Zeklen 10/40 mg [AF] | |

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

| 13595M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *37.47 | 30.00 | [a] APO-Ezetimibe/Simvastatin 10/80 [TX] | [a] EZESIM 10/80 [RZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] | [a] EZETORIN [RW] |
| | | | | | | [a] EZEVYT 10/80 [LR] | [a] EzSimva GH 10/80 [GQ] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/80 [CR] | [a] Vytorin [AL] |
| | | | | | | [a] Zeklen 10/80 mg [AF] | |

*Lipid modifying agents in combination with other drugs*

## ▪ AMLODIPINE + ATORVASTATIN

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

| 9053L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.63 | 18.03 | [a] Cadivast 10/10 [AF] |
| | | | [B]5.00 | 21.63 | 18.03 | [a] Caduet 10/10 [AS] |

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

| 9054M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.83 | 18.23 | [a] Cadivast 10/20 [AF] |
| | | | [B]5.00 | 21.83 | 18.23 | [a] Caduet 10/20 [AS] |

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

| 9055N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.74 | 19.14 | [a] Cadivast 10/40 [AF] |
| | | | [B]5.00 | 22.74 | 19.14 | [a] Caduet 10/40 [AS] |

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

| 9056P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.11 | 20.51 | [a] Cadivast 10/80 [AF] |
| | | | [B]5.00 | 24.11 | 20.51 | [a] Caduet 10/80 [AS] |

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

| 9049G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 15.95 | 17.35 | Cadivast 5/10 [AF] |

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

| 9050H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 16.68 | 18.08 | Cadivast 5/20 [AF] |

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

| 9051J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.05 | 18.45 | [a] Cadivast 5/40 [AF] |
| | | | [B]5.00 | 22.05 | 18.45 | [a] Caduet 5/40 [AS] |

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9052K NP | 1 | 5 | .. | 18.42 | 19.82 | [a] Cadivast 5/80 [AF] |
| | | | [B]5.00 | 23.42 | 19.82 | [a] Caduet 5/80 [AS] |

## ▪ AMLODIPINE + ATORVASTATIN

**Restricted benefit**

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

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13479K NP | 2 | 5 | .. | *20.27 | 21.67 | [a] Cadivast 10/10 [AF] |
| | | | [B]10.00 | *30.27 | 21.67 | [a] Caduet 10/10 [AS] |

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13384K NP | 2 | 5 | .. | *20.67 | 22.07 | [a] Cadivast 10/20 [AF] |
| | | | [B]10.00 | *30.67 | 22.07 | [a] Caduet 10/20 [AS] |

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13536K NP | 2 | 5 | .. | *22.49 | 23.89 | [a] Cadivast 10/40 [AF] |
| | | | [B]10.00 | *32.49 | 23.89 | [a] Caduet 10/40 [AS] |

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13596N NP | 2 | 5 | .. | *18.91 | 20.31 | Cadivast 5/10 [AF] |

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13567C NP | 2 | 5 | .. | *20.37 | 21.77 | Cadivast 5/20 [AF] |

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13415C NP | 2 | 5 | .. | *21.11 | 22.51 | [a] Cadivast 5/40 [AF] |
| | | | [B]10.00 | *31.11 | 22.51 | [a] Caduet 5/40 [AS] |

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13597P NP | 2 | 5 | .. | *23.85 | 25.25 | [a] Cadivast 5/80 [AF] |
| | | | [B]10.00 | *33.85 | 25.25 | [a] Caduet 5/80 [AS] |

# ▪ DERMATOLOGICALS

# ▪ ANTIFUNGALS FOR DERMATOLOGICAL USE

## ANTIFUNGALS FOR TOPICAL USE

*Imidazole and triazole derivatives*

## ▪ KETOCONAZOLE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**ketoconazole 2% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9024Y NP | ‡1 | 2 | .. | 24.30 | 25.70 | Nizoral 2% Cream [JT] |

## ▪ MICONAZOLE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**miconazole nitrate 2% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9027D NP | ‡1 | 2 | .. | 18.56 | 19.96 | Daktarin [JT] |

**miconazole nitrate 2% cream, 70 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9028E NP | ‡1 | 1 | .. | 19.77 | 21.17 | Daktarin [JT] |

**miconazole nitrate 2% powder, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9029F NP | ‡1 | 2 | .. | 19.06 | 20.46 | Daktarin [JT] |

**miconazole 2% solution, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9031H NP | ‡1 | 2 | .. | 21.46 | 22.86 | Daktarin Tincture [JT] |

*Other antifungals for topical use*

## ▪ TERBINAFINE

**Authority required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***6412***

Fungal or yeast infection

**Clinical criteria:**

- The condition must be fungal; OR
- The condition must be due to yeast.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine hydrochloride 1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9160D NP | 2 | 3 | .. | *39.89 | 30.00 | Lamisil [GJ] |

## ANTIFUNGALS FOR SYSTEMIC USE

*Antifungals for systemic use*

## ▪ GRISEOFULVIN

**griseofulvin 125 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1460W NP | 1 | 2 | .. | 23.67 | 25.07 | Grisovin [AS] |

**griseofulvin 500 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2982Y NP | 1 | 2 | .. | 24.30 | 25.70 | Grisovin 500 [AS] |

## ▪ TERBINAFINE

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2285G NP | 1 | .. | .. | 28.35 | 29.75 | [a] APO-Terbinafine [TX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | | [a] NOUMED TERBINAFINE [VO] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine-DRLA [RZ] | [a] Terbinafine Sandoz [SZ] |
| | | | | | | [a] Tinasil [AF] | |

## ▪ TERBINAFINE

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

**Authority required**
Onychomycosis
**Clinical criteria:**
- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

**terbinafine 250 mg tablet, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2804N NP | 1 | 1 | .. | 28.35 | 29.75 | [a] APO-Terbinafine [TX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | | [a] NOUMED TERBINAFINE [VO] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine-DRLA [RZ] | [a] Terbinafine Sandoz [SZ] |
| | | | | | | [a] Tinasil [AF] | |

# ▪ ANTIPSORIATICS

## ANTIPSORIATICS FOR TOPICAL USE

*Other antipsoriatics for topical use*

## ▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

**Restricted benefit**
Chronic stable plaque type psoriasis vulgaris
**Clinical criteria:**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9494Q NP | ‡1 | 1 | .. | 39.00 | 30.00 | [a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ] | [a] Daivobet [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11091R NP | ‡1 | 1 | .. | 85.23 | 30.00 | Enstilar [LO] |

## ▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

**Restricted benefit**
Chronic stable plaque type psoriasis vulgaris
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13577N NP | ‡2 | 1 | .. | *65.01 | 30.00 | [a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ] | [a] Daivobet [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13520N NP | ‡2 | 1 | .. | *159.69 | 30.00 | Enstilar [LO] |

## ANTIPSORIATICS FOR SYSTEMIC USE

*Retinoids for treatment of psoriasis*

## ▪ ACITRETIN

**Caution** This drug is a potent teratogen - pregnancy should be avoided during therapy and for at least three years after cessation of therapy.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

***5789***

Severe intractable psoriasis

**Authority required (STREAMLINED)**

***5727***

Severe disorders of keratinisation

**acitretin 10 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2019G | 1 | 2 | .. | 109.24 | 30.00 | [a] Neotigason [TB] | [a] ZETIN [RW] |

**acitretin 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2020H | 1 | 2 | .. | 213.52 | 30.00 | [a] Neotigason [TB] | [a] ZETIN [RW] |

# ▪ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

## CHEMOTHERAPEUTICS FOR TOPICAL USE

*Sulfonamides*

## ▪ SILVER SULFADIAZINE

**Restricted benefit**

Infection

Treatment Phase: Prevention and treatment

**Clinical criteria:**

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

**Restricted benefit**

Stasis ulcers

**silver sulfadiazine 1% cream, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9479X NP | ‡1 | .. | .. | 22.46 | 23.86 | Flamazine [SN] |

# ▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

## CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

## ▪ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2881P NP | ‡1 | 1 | .. | 15.90 | 17.30 | [a] Cortic-DS 1% [LN] |
| | | | [B]2.19 | 18.09 | 17.30 | [a] Sigmacort [AS] |

**hydrocortisone acetate 1% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2882Q NP | ‡1 | 1 | .. | 15.90 | 17.30 | [a] Cortic-DS 1% [LN] |
| | | | [B]2.19 | 18.09 | 17.30 | [a] Sigmacort [AS] |

## ▪ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5113D DP | ‡1 | .. | .. | 15.90 | 17.30 | [a] Cortic-DS 1% [LN] |
| | | | [B]2.19 | 18.09 | 17.30 | [a] Sigmacort [AS] |

**hydrocortisone acetate 1% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5114E DP | ‡1 | .. | .. | 15.90 | 17.30 | [a] Cortic-DS 1% [LN] |
| | | | [B]2.19 | 18.09 | 17.30 | [a] Sigmacort [AS] |

*Corticosteroids, moderately potent (group II)*

## ▪ TRIAMCINOLONE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**triamcinolone acetonide 0.02% cream, 100 g**

2117K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *20.51 | 21.91 | [a] Tricortone [LN] |
| | | [B]3.28 | *23.79 | 21.91 | [a] Aristocort 0.02% [AS] |

**triamcinolone acetonide 0.02% ointment, 100 g**

2118L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *20.51 | 21.91 | [a] Tricortone [LN] |
| | | [B]3.28 | *23.79 | 21.91 | [a] Aristocort 0.02% [AS] |

*Corticosteroids, potent (group III)*

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as dipropionate) 0.05% cream, 15 g**

1115Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 16.91 | 18.31 | [a] Eleuphrat [OV] |
| | | [B]2.45 | 19.36 | 18.31 | [a] Diprosone [OQ] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

1119X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 16.91 | 18.31 | [a] Eleuphrat [OV] |
| | | [B]2.45 | 19.36 | 18.31 | [a] Diprosone [OQ] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10824Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *20.83 | 22.23 | [a] Eleuphrat [OV] |
| | | [B]4.90 | *25.73 | 22.23 | [a] Diprosone [OQ] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10795E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *20.83 | 22.23 | [a] Eleuphrat [OV] |
| | | [B]4.90 | *25.73 | 22.23 | [a] Diprosone [OQ] |

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10800K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *28.69 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]9.80 | *38.49 | 30.00 | [a] Diprosone [OQ] |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10820L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *28.69 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]9.80 | *38.49 | 30.00 | [a] Diprosone [OQ] |

NP

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10813D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *36.51 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]14.70 | *51.21 | 30.00 | [a] Diprosone [OQ] |

NP

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10821M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *36.51 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]14.70 | *51.21 | 30.00 | [a] Diprosone [OQ] |

NP

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10801L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *44.37 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]19.60 | *63.97 | 30.00 | [a] Diprosone [OQ] |

NP

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10816G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *44.37 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]19.60 | *63.97 | 30.00 | [a] Diprosone [OQ] |

NP

## ▪ BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10802M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 5 | .. | *52.17 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]24.50 | *76.67 | 30.00 | [a] Diprosone [OQ] |

NP

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10823P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 5 | .. | *52.17 | 30.00 | [a] Eleuphrat [OV] |
| | | [B]24.50 | *76.67 | 30.00 | [a] Diprosone [OQ] |

NP

## ▪ BETAMETHASONE VALERATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.02% cream, 100 g**

2812B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *23.59 | 24.99 | [a] Antroquoril [OV] |
| | | | | | [b] Cortival 1/5 [LN] |
| | | [B]4.10 | *27.69 | 24.99 | [b] Betnovate 1/5 [AS] |
| | | [B]5.00 | *28.59 | 24.99 | [a] Celestone-M [OQ] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.05% cream, 15 g**

2813C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 15.68 | 17.08 | [a] Cortival 1/2 [LN] |
| | | [B]2.56 | 18.24 | 17.08 | [a] Betnovate 1/2 [AS] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10799J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *18.37 | 19.77 | [a] Cortival 1/2 [LN] |
| | | [B]5.12 | *23.49 | 19.77 | [a] Betnovate 1/2 [AS] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10794D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *23.77 | 25.17 | [a] Cortival 1/2 [LN] |
| | | [B]10.24 | *34.01 | 25.17 | [a] Betnovate 1/2 [AS] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10808W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *29.13 | 30.00 | [a] Cortival 1/2 [LN] |
| | | [B]15.36 | *44.49 | 30.00 | [a] Betnovate 1/2 [AS] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10807T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *34.53 | 30.00 | [a] Cortival 1/2 [LN] |
| | | [B]20.48 | *55.01 | 30.00 | [a] Betnovate 1/2 [AS] |

## ▪ BETAMETHASONE VALERATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10810Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 5 | .. | *39.87 | 30.00 | [a] Cortival 1/2 [LN] |
| | | [B]25.60 | *65.47 | 30.00 | [a] Betnovate 1/2 [AS] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**methylprednisolone aceponate 0.1% ointment, 15 g**

8055Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 18.31 | 19.71 | Advantan [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

8128T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 18.31 | 19.71 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

8054X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 18.31 | 19.71 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Eczema

**methylprednisolone aceponate 0.1% lotion, 20 g**

8618N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 18.96 | 20.36 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10846W NP | 2 | 5 | .. | *23.63 | 25.03 | Advantan [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10848Y NP | 2 | 5 | .. | *23.63 | 25.03 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10842P NP | 2 | 5 | .. | *23.63 | 25.03 | Advantan [LO] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10856J NP | 2 | 5 | .. | *24.93 | 26.33 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10836H NP | 4 | 5 | .. | *34.29 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10840M NP | 4 | 5 | .. | *34.29 | 30.00 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10855H NP | 4 | 5 | .. | *34.29 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10838K NP | 3 | 5 | .. | *30.90 | 30.00 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10843Q NP | 10 | 5 | .. | *66.17 | 30.00 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10845T NP | 10 | 5 | .. | *66.17 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10833E NP | 10 | 5 | .. | *66.17 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10830B NP | 5 | 5 | .. | *42.82 | 30.00 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10844R NP | 6 | 5 | .. | *44.91 | 30.00 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10853F NP | 6 | 5 | .. | *44.91 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10835G NP | 6 | 5 | .. | *44.91 | 30.00 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10834F NP | 8 | 5 | .. | *55.57 | 30.00 | Advantan [LO] |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10839L NP | 8 | 5 | .. | *55.57 | 30.00 | Advantan (Fatty) [LO] |

**methylprednisolone aceponate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10851D NP | 8 | 5 | .. | *55.57 | 30.00 | Advantan [LO] |

## ▪ METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

10852E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *36.89 | 30.00 | Advantan [LO] |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

**mometasone furoate 0.1% cream, 15 g**

1913Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.75 | 18.15 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | [B]3.53 | 20.28 | 18.15 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% lotion, 30 mL**

8043H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 18.22 | 19.62 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | [B]3.53 | 21.75 | 19.62 | [a] Elocon [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

1915T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.75 | 18.15 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | [B]3.53 | 20.28 | 18.15 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10827W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | [B]7.06 | *27.57 | 21.91 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% lotion, 30 mL**

10819K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *23.45 | 24.85 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | [B]7.06 | *30.51 | 24.85 | [a] Elocon [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

10812C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.51 | 21.91 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | [B]7.06 | *27.57 | 21.91 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10809X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *28.05 | 29.45 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | | [B]14.12 | *42.17 | 29.45 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% lotion, 30 mL**

| 10826T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 5 | .. | *28.68 | 30.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]10.59 | *39.27 | 30.00 | [a] Elocon [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10814E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | .. | *28.05 | 29.45 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]14.12 | *42.17 | 29.45 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10815F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *35.55 | 30.00 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | | [B]21.18 | *56.73 | 30.00 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10828X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | .. | *35.55 | 30.00 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]21.18 | *56.73 | 30.00 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10818J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *43.09 | 30.00 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | | [B]28.24 | *71.33 | 30.00 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10793C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *43.09 | 30.00 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]28.24 | *71.33 | 30.00 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10792B NP | 10 | 5 | .. | *50.57 | 30.00 | [a] Momasone Alcohol Free [AS] | [a] Novasone [AF] |
| | | | [B]35.30 | *85.87 | 30.00 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% lotion, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10804P NP | 5 | 5 | .. | *39.12 | 30.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]17.65 | *56.77 | 30.00 | [a] Elocon [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10791Y NP | 10 | 5 | .. | *50.57 | 30.00 | [a] Momasone [AS]<br>[a] Zatamil [EO] | [a] Novasone [AF] |
| | | | [B]35.30 | *85.87 | 30.00 | [a] Elocon [AL] | |

## ▪ MOMETASONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10805Q NP | 4 | 5 | .. | *33.93 | 30.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]14.12 | *48.05 | 30.00 | [a] Elocon [AL] | |

*Corticosteroids, very potent (group IV)*

## ▪ CLOBETASOL

**Authority required (STREAMLINED)**

***5461***

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be aged 18 years or older.

**clobetasol propionate 0.05% shampoo, 125 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10080M | ‡1 | 1 | .. | 48.83 | 30.00 | Clobex [GA] |

# ▪ ANTI-ACNE PREPARATIONS

## ANTI-ACNE PREPARATIONS FOR TOPICAL USE

*Retinoids for topical use in acne*

## ▪ ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

Severe acne vulgaris

Treatment Phase: Acute treatment

**Clinical criteria:**

- The treatment must in combination with an oral antibiotic.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8954G | ‡1 | 1 | .. | 35.68 | 30.00 | Epiduo [GA] |

## ▪ ADAPALENE + BENZOYL PEROXIDE

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

**Restricted benefit**
Severe acne vulgaris
**Clinical criteria:**
- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

8955H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 35.68 | 30.00 | Epiduo [GA] |

NP

## ▪ ADAPALENE + BENZOYL PEROXIDE

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

**Restricted benefit**
Severe acne vulgaris
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

13363H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 3 | .. | *58.37 | 30.00 | Epiduo [GA] |

NP

# ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

*Retinoids for treatment of acne*

## ▪ ISOTRETINOIN

**Caution** This drug causes birth defects.
This drug has been reported to cause other frequent and potentially serious toxicity.
**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**
***5224***
Severe cystic acne
**Clinical criteria:**
- The condition must be unresponsive to other therapy.

**isotretinoin 5 mg capsule, 60**

11716P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 24.83 | 26.23 | Oratane [OU] |

**isotretinoin 30 mg capsule, 60**

11921K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 62.95 | 30.00 | Oratane [OU] |

**isotretinoin 10 mg capsule, 60**

2591J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 36.67 | 30.00 | [a] APO-Isotretinoin [TX] | [a] Dermatane [ZS] |
| | | | | | [a] Isotretinoin GX [SZ] | [a] Isotretinoin Lupin [GQ] |
| | | | | | [a] Oratane [RF] | [a] Rocta 10 [RW] |

**isotretinoin 40 mg capsule, 30**

2549E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 46.30 | 30.00 | [a] Dermatane [ZS] | [a] Oratane [RF] |

## ▪ ISOTRETINOIN

**Caution** This drug causes birth defects.
This drug has been reported to cause other frequent and potentially serious toxicity.
**Note** Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.
**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

***5224***
Severe cystic acne
**Clinical criteria:**
- The condition must be unresponsive to other therapy.

**isotretinoin 20 mg capsule, 30**

11621P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *49.89 | 30.00 | [a] Roaccutane [RO] |

**isotretinoin 20 mg capsule, 60**

2592K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 49.89 | 30.00 | [a] APO-Isotretinoin [TX] | [a] Dermatane [ZS] |
| | | | | | [a] Isotretinoin GX [SZ] | [a] Isotretinoin Lupin [GQ] |
| | | | | | [a] Isotretinoin SCP 20 [CR] | [a] Oratane [RF] |
| | | | | | [a] Rocta 20 [RW] | |

## ▪ OTHER DERMATOLOGICAL PREPARATIONS

### OTHER DERMATOLOGICAL PREPARATIONS

*Agents for dermatitis, excluding corticosteroids*

### ▪ DUPILUMAB

**Note** Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here: https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Note** Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR

- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

**dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12292Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1755.19 | 30.00 | Dupixent [SW] |

**dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12291X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1755.19 | 30.00 | Dupixent [SW] |

## ▪ PIMECROLIMUS

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

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

**Authority required (STREAMLINED)**

***5482***

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)**

***5472***

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**pimecrolimus 1% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8802G | ‡1 | 1 | .. | 28.02 | 29.42 | Elidel [GO] |

*Other dermatologicals*

## ▪ DAPSONE

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

**dapsone 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1272Y NP | 1 | 1 | .. | 400.67 | 30.00 | Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8801F NP | 1 | 1 | .. | 327.98 | 30.00 | Link Medical Products Pty Ltd [LM] |

## ▪ IMIQUIMOD

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Treatment of recurrent (previously treated) lesions will not be authorised.
**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**
Superficial basal cell carcinoma
**Clinical criteria:**

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**imiquimod 5% cream, 2 x 2 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2637T | 1 | 1 | [B]8.35 | 96.87 | 30.00 | [a] Aldara Pump [IL] |

**imiquimod 5% cream, 12 x 250 mg sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2546B | 1 | 1 | .. | 88.52 | 30.00 | [a] Aldiq [AF] | [a] APO-Imiquimod [TX] |
| | | | [B]3.30 | 91.82 | 30.00 | [a] Aldara [IL] | |

# ▪ GENITO URINARY SYSTEM AND SEX HORMONES

# ▪ OTHER GYNECOLOGICALS

## CONTRACEPTIVES FOR TOPICAL USE

*Intrauterine contraceptives*

## ▪ LEVONORGESTREL

**Restricted benefit**
Contraception

**levonorgestrel 19.5 mg intrauterine drug delivery system, 1 system**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11909T NP | 1 | .. | .. | 171.32 | 30.00 | Kyleena [SY] |

## ▪ LEVONORGESTREL

**Restricted benefit**
Contraception
**Restricted benefit**
Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are ineffective.

**Restricted benefit**

Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

8633J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 168.39 | 30.00 | Mirena [BN] |

## OTHER GYNECOLOGICALS

*Prolactine inhibitors*

### ▪ BROMOCRIPTINE

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

1444B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 22.62 | 24.02 | Parlodel [SZ] |

### ▪ BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *32.25 | 30.00 | Parlodel [SZ] |

### ▪ CABERGOLINE

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**cabergoline 500 microgram tablet, 2**

8115D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 26.35 | 27.75 | Dostinex [PF] |

### ▪ CABERGOLINE

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

8114C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 66.45 | 30.00 | Dostinex [PF] |

## ▪ QUINAGOLIDE

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**quinagolide 75 microgram tablet, 30**

8822H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 74.88 | 30.00 | Norprolac [FP] |

# ▪ SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

## HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

*Progestogens and estrogens, fixed combinations*

## ▪ LEVONORGESTREL + ETHINYLESTRADIOL

**levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2416E

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 19.10 | 20.50 | Femme-Tab ED 20/100 [AE] |

**levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1456P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 22.86 | 24.26 | Microgynon 50 ED [BN] |

**levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1394J

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 18.15 | 19.55 | Monofeme 28 [FZ]<br>[a] Eleanor 150/30 ED [EA]<br>[a] Femme-Tab ED 30/150 [AE]<br>[a] Micronelle 30 ED [TX] | [a] Evelyn 150/30 ED [GQ]<br>[a] Lenest 30 ED [AF] |
| | | [B]4.91 | 23.06 | 19.55 | [a] Levlen ED [SY] | |

## ▪ NORETHISTERONE + ETHINYLESTRADIOL

**norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2774B

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 18.97 | 20.37 | Norimin 28 Day [FZ] |

## ▪ NORETHISTERONE + ETHINYLESTRADIOL

**Note** Pharmaceutical benefits that have the form norethisterone 1 mg + ethinylestradiol 35 microgram tablet in a 4 pack of 28 tablets can be substituted for a 3 pack of 28 tablets in the case of a shortage.

**norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2775C NP | 1 | 2 | .. | 18.97 | 20.37 | Norimin-1 28 Day [FZ] |

*Progestogens and estrogens, sequential preparations*

## ▪ LEVONORGESTREL + ETHINYLESTRADIOL

**levonorgestrel 50 microgram + ethinylestradiol 30 microgram tablet [6] (&) levonorgestrel 75 microgram + ethinylestradiol 40 microgram tablet [5] (&) levonorgestrel 125 microgram + ethinylestradiol 30 microgram tablet [10] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1392G NP | 1 | 2 | .. | 20.71 | 22.11 | Trifeme 28 [FZ] |
| | | | | | | [a] Logynon ED [SY] |
| | | | [B]13.56 | 34.27 | 22.11 | [a] Triquilar ED [BN] |

*Progestogens*

## ▪ ETONOGESTREL

**etonogestrel 68 mg implant, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8487Q NP MW | 1 | .. | .. | 171.32 | 30.00 | Implanon NXT [OQ] |

## ▪ LEVONORGESTREL

**levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2913H NP MW | 1 | 2 | .. | 20.69 | 22.09 | Microlut 28 [BN] |

## ▪ MEDROXYPROGESTERONE

**medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3118D NP | 1 | 1 | .. | 27.12 | 28.52 | [a] Depo-Ralovera [FZ] |
| | | | [B]7.00 | 34.12 | 28.52 | [a] Depo-Provera [PF] |

## ▪ NORETHISTERONE

**norethisterone 350 microgram tablet, 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1967M NP | 1 | 2 | .. | 18.97 | 20.37 | Noriday 28 Day [PF] |

# ANDROGENS

*3-oxoandrosten (4) derivatives*

## ▪ TESTOSTERONE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum area.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

**testosterone 5% (50 mg/mL) cream, 50 mL**

10378F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 107.07 | 30.00 | AndroForte 5 [LX] |

## ▪ TESTOSTERONE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone 2% (23 mg/actuation) gel, 56 actuations**

11740X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 83.94 | 30.00 | Testavan [IX] |

**testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations**

10380H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 4 | .. | 78.49 | 30.00 | Testogel [HB] |

**testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets**

8830R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 78.49 | 30.00 | Testogel [HB] |

## ▪ TESTOSTERONE UNDECANOATE

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial**

10205D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 93.96 | 30.00 | Reandron 1000 [BN] |

## ESTROGENS

*Natural and semisynthetic estrogens, plain*

### ▪ ESTRADIOL

**Note Continuing Therapy Only:**

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

**estradiol 10 microgram modified release pessary, 18**

10203B

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 29.55 | 30.00 | [a] Estro-Pess [AS] | [a] Vagifem Low [NO] |

**estradiol valerate 1 mg tablet, 56**

1663M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 16.31 | 17.71 | Progynova [BN] |

**estradiol valerate 2 mg tablet, 56**

1664N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 17.54 | 18.94 | Progynova [BN] |

**estradiol 2 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8274L NP | 1 | 2 | .. | 19.19 | 20.59 | Zumenon [GO] |

## ▪ ESTRADIOL

**Note** Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**Note Continuing Therapy Only:**

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

**estradiol 37.5 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8762E NP | ‡1 | 5 | .. | 29.81 | 30.00 | Estradot 37.5 [SZ] |

**estradiol 75 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8764G NP | ‡1 | 5 | .. | 28.98 | 30.00 | Estradot 75 [SZ] |

**estradiol 100 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8312L NP | ‡1 | 5 | .. | 20.56 | 21.96 | Estraderm MX 100 [JU] |

**estradiol 100 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8765H NP | ‡1 | 5 | .. | 28.37 | 29.77 | Estradot 100 [SZ] |

**estradiol 50 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8140K NP | ‡1 | 5 | .. | 19.34 | 20.74 | Estraderm MX 50 [JU] |

**estradiol 50 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8763F NP | ‡1 | 5 | .. | 27.72 | 29.12 | Estradot 50 [SZ] |

**estradiol 25 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8311K NP | ‡1 | 5 | .. | 19.34 | 20.74 | Estraderm MX 25 [JU] |

**estradiol 25 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8761D NP | ‡1 | 5 | .. | 28.46 | 29.86 | Estradot 25 [SZ] |

**estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8286D NP | ‡1 | 5 | .. | 22.27 | 23.67 | Sandrena [OX] |

**estradiol 25 microgram/24 hours patch, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8485N NP | ‡1 | 5 | .. | 19.34 | 20.74 | Climara 25 [BN] |

**estradiol 50 microgram/24 hours patch, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8125P NP | ‡1 | 5 | .. | 19.34 | 20.74 | Climara 50 [BN] |

**estradiol 75 microgram/24 hours patch, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8486P NP | ‡1 | 5 | .. | 20.56 | 21.96 | Climara 75 [BN] |

**estradiol 100 microgram/24 hours patch, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8126Q NP | ‡1 | 5 | .. | 20.56 | 21.96 | Climara 100 [BN] |

## ▪ ESTRIOL

**Note Continuing Therapy Only:**

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

**estriol 500 microgram pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1771F NP | ‡1 | 2 | .. | 25.80 | 27.20 | Ovestin Ovula [AS] |

**estriol 0.1% (1 mg/g) cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1781R NP | ‡1 | 1 | .. | 24.31 | 25.71 | Ovestin [AS] |

## PROGESTOGENS

*Pregnen (4) derivatives*

### ▪ MEDROXYPROGESTERONE

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

**medroxyprogesterone acetate 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2321E NP | 1 | 2 | .. | 19.86 | 21.26 | [a] Ralovera [FZ] |
| | | | [B]6.70 | 26.56 | 21.26 | [a] Provera [PF] |

**medroxyprogesterone acetate 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2323G NP | 1 | 2 | .. | 18.50 | 19.90 | [a] Ralovera [FZ] |
| | | | [B]4.55 | 23.05 | 19.90 | [a] Provera [PF] |

### ▪ MEDROXYPROGESTERONE

**Restricted benefit**
Endometriosis

**medroxyprogesterone acetate 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2722G | 1 | 2 | .. | 35.89 | 30.00 | [a] Ralovera [FZ] |
| | | | [B]6.70 | 42.59 | 30.00 | [a] Provera [PF] |

### ▪ PROGESTERONE

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

**Authority required (STREAMLINED)**
***11835***
Prevention of preterm birth
**Clinical criteria:**

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12598C NP MW | 1 | 3 | .. | 94.20 | 30.00 | Utrogestan [HB] |

### ▪ PROGESTERONE

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

**Authority required (STREAMLINED)**
***11673***
Prevention of preterm birth
**Clinical criteria:**

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12465C NP MW | 3 | 3 | .. | *127.89 | 30.00 | Oripro [ON] |

*Estren derivatives*

## ▪ NORETHISTERONE

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

**norethisterone 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2993M NP | 1 | 2 | .. | 35.20 | 30.00 | Primolut N [BN] |

## PROGESTOGENS AND ESTROGENS IN COMBINATION

*Progestogens and estrogens, fixed combinations*

## ▪ ESTRADIOL + DYDROGESTERONE

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

**estradiol 1 mg + dydrogesterone 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10142T NP | 1 | 5 | .. | 20.34 | 21.74 | Femoston-Conti [GO] |

## ▪ ESTRADIOL + NORETHISTERONE ACETATE

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

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8428N NP | ‡1 | 5 | .. | 34.26 | 30.00 | Estalis continuous 50/250 [SZ] |

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8427M NP | ‡1 | 5 | .. | 33.26 | 30.00 | Estalis continuous 50/140 [SZ] |

*Progestogens and estrogens, sequential preparations*

## ▪ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE

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

**estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10146B NP | ‡1 | 5 | .. | 23.72 | 25.12 | Femoston 1/10 [GO] |

**estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8244X NP | ‡1 | 5 | .. | 23.72 | 25.12 | Femoston 2/10 [GO] |

## ▪ NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL

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

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8426L NP | ‡1 | 5 | .. | 42.82 | 30.00 | Estalis sequi 50/250 [SZ] |

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8425K NP | ‡1 | 5 | .. | 40.67 | 30.00 | Estalis sequi 50/140 [SZ] |

## GONADOTROPINS AND OTHER OVULATION STIMULANTS

*Gonadotropins*

### ▪ CHORIOGONADOTROPIN ALFA

**Restricted benefit**

Infertility indications other than that of Assisted Reproductive Technology

**Treatment criteria:**

- Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule, **AND**
- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing, **AND**
- Must be treated by an obstetrician/gynaecologist; OR
- Must be treated by a specialist in reproductive endocrinology/infertility; OR
- Must be treated by a urogynaecologist; OR
- Must be treated by an endocrinologist; OR
- Must be treated by a urologist.

The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device**

13300B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 63.36 | 30.00 | Ovidrel [SG] |

### ▪ FOLLITROPIN ALFA

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand, Bemfola or Ovaleap, is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge**

12769C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *300.69 | 30.00 | [a] Ovaleap [TT] |

**follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge**

12808D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *447.03 | 30.00 | [a] Ovaleap [TT] |

**follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge**

12778M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *747.43 | 30.00 | [a] Ovaleap [TT] |

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices**

10876K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 1 | .. | *1034.64 | 30.00 | Bemfola [FX] |

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10865W | 3 | 1 | .. | *355.56 | 30.00 | Bemfola [FX] |

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10877L | 3 | 1 | .. | *703.14 | 30.00 | Bemfola [FX] |

**follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8713N | 3 | 5 | .. | *300.69 | 30.00 | [a] Gonal-f Pen [SG] |

**follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8714P | 3 | 5 | .. | *447.03 | 30.00 | [a] Gonal-f Pen [SG] |

**follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8715Q | 2 | 5 | .. | *747.43 | 30.00 | [a] Gonal-f Pen [SG] |

## ▪ FOLLITROPIN BETA

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8565T | 3 | 5 | .. | *317.49 | 30.00 | [a] Puregon 300 IU/0.36 mL [OQ] | [a] Recagon [OV] |

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8566W | 2 | 5 | .. | *410.63 | 30.00 | [a] Puregon 600 IU/0.72 mL [OQ] | [a] Recagon [OV] |

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8871X | 2 | 5 | .. | *606.53 | 30.00 | [a] Puregon 900 IU/1.08 mL [OQ] | [a] Recagon [OV] |

## ▪ HUMAN CHORIONIC GONADOTROPHIN

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism.

**Restricted benefit**

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

**Restricted benefit**

Combined deficiency of human growth hormone and gonadotrophins

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

**Restricted benefit**

Hypogonadism or delayed puberty

**Population criteria:**

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

**Clinical criteria:**

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

12905F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 96.95 | 30.00 | Brevactid 1500 I.E [DZ] |

*Ovulation stimulants, synthetic*

## ▪ CLOMIFENE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

Patients undergoing in-vitro fertilisation

**clomifene citrate 50 mg tablet, 10**

1211R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 34.66 | 30.00 | Clomid [SW] |

## ANTIANDROGENS

*Antiandrogens, plain*

## ▪ CYPROTERONE

**cyproterone acetate 100 mg tablet, 50**

8019C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 60.80 | 30.00 | [a] ANTERONE 100 [RW]<br>[a] Cyprone 100 [AF]<br>[a] GenRx Cyproterone Acetate [GX] | [a] APO-Cyproterone [TX]<br>[a] Cyproterone Sandoz [HX]<br>[a] Pharmacor Cyproterone 100 [CR] |
| | | [B]1.21 | 62.01 | 30.00 | [a] Androcur-100 [BN] | |

**cyproterone acetate 50 mg tablet, 50**

1270W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *74.39 | 30.00 | [a] ANTERONE 50 [RW]<br>[a] Cyprone 50 [AL]<br>[a] GenRx Cyproterone Acetate [GX] | [a] APO-Cyproterone [TX]<br>[a] Cyproterone Sandoz [HX]<br>[a] Pharmacor Cyproterone 50 [CR] |
| | | [B]1.96 | *76.35 | 30.00 | [a] Androcur [BN] | |

## ▪ CYPROTERONE

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority required (STREAMLINED)**

***5532***

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1269T | 1 | 5 | .. | 25.27 | 26.67 | [a] ANTERONE 50 [RW]<br>[a] Cyprone 50 [AL]<br>[a] GenRx Cyproterone Acetate [GX] | [a] APO-Cyproterone [TX]<br>[a] Cyproterone Sandoz [HX]<br>[a] Pharmacor Cyproterone 50 [CR] |

## OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

*Progesterone receptor modulators*

### ▪ MIFEPRISTONE (&) MISOPROSTOL

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***14202***
Termination of an intra-uterine pregnancy
**Clinical criteria:**

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

**mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10211K (NP) (MW) | ‡1 | .. | .. | 354.69 | 30.00 | MS-2 Step [XH] |

# ▪ UROLOGICALS

## UROLOGICALS

*Drugs for urinary frequency and incontinence*

### ▪ OXYBUTYNIN

**Restricted benefit**
Detrusor overactivity

**oxybutynin hydrochloride 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8039D (NP) | 1 | 5 | .. | 16.94 | 18.34 | Ditropan [SW] |

### ▪ OXYBUTYNIN

**Restricted benefit**
Detrusor overactivity
**Clinical criteria:**

- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

**oxybutynin 3.9 mg/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9454N (NP) | ‡1 | 5 | .. | 29.47 | 30.00 | Oxytrol [TT] |

### ▪ PROPANTHELINE

**Restricted benefit**
Detrusor overactivity

**propantheline bromide 15 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1953T (NP) | 2 | 5 | .. | *24.01 | 25.41 | Pro-Banthine [RW] |

*Other urologicals*

### ▪ BICARBONATE

**sodium bicarbonate 840 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9470K (NP) | 1 | 2 | .. | 21.18 | 22.58 | Sodibic [AS] |

### ▪ PHENOXYBENZAMINE

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

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

1862B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 752.30 | 30.00 | Dibenyline [GH] |

NP

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

1166J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *677.88 | 30.00 | Amdipharm Mercury (Australia) Pty Limited [GH] |

NP

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

*Alpha-adrenoreceptor antagonists*

### ▪ DUTASTERIDE + TAMSULOSIN

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6189***

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

5490Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 30.89 | 30.00 | [a] Doubluts [GC] |
| | | [B]3.50 | 34.39 | 30.00 | [a] Duodart 500ug/400ug [GK] |

NP

*Testosterone-5-alpha reductase inhibitors*

### ▪ DUTASTERIDE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

***6202***

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

5468T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 29.35 | 30.00 | [a] APO-Dutasteride [TX] |
| | | [B]7.00 | 36.35 | 30.00 | [a] Avodart [GK] |

NP

# ▪ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

# ▪ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

## ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*ACTH*

### ▪ TETRACOSACTIDE

**Restricted benefit**

Hypsarrhythmia and/or infantile spasms

**tetracosactide 1 mg/mL modified release injection, 1 mL ampoule**

2832C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 5 | .. | *308.27 | 30.00 | Synacthen Depot 1 mg/1 mL [IX] |

*Thyrotropin*

### ▪ THYROTROPIN ALFA

**Restricted benefit**

Ablation of thyroid remnant tissue

**Clinical criteria:**

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

**thyrotropin alfa 900 microgram injection, 2 vials**

2700D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1561.66 | 30.00 | Thyrogen [GZ] |

## POSTERIOR PITUITARY LOBE HORMONES

*Vasopressin and analogues*

### ▪ DESMOPRESSIN

**Authority required (STREAMLINED)**

***5266***

Cranial diabetes insipidus

**desmopressin acetate 200 microgram tablet, 30**

8662X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *112.62 | 30.00 | Minirin [FP] |

### ▪ DESMOPRESSIN

**Note** Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

**Authority required (STREAMLINED)**

***5266***

Cranial diabetes insipidus

**desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations**

12458Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *232.23 | 30.00 | [a] Desmopressin Nasal Spray USP (Apotex) [DZ] |

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

8711L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *101.79 | 30.00 | [a] Minirin Nasal Spray [FP] |

### ▪ DESMOPRESSIN

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**Authority required (STREAMLINED)**

***5413***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5295***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 200 microgram tablet, 30**

8663Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 46.20 | 30.00 | Minirin [FP] |

### ▪ DESMOPRESSIN

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**Authority required (STREAMLINED)**

***5412***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5226***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin 120 microgram sublingual wafer, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9398P NP | 1 | 5 | .. | 50.00 | 30.00 | Minirin Melt [FP] |

**desmopressin 240 microgram sublingual wafer, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8975J NP | 1 | 5 | .. | 75.89 | 30.00 | Minirin Melt [FP] |

## ▪ DESMOPRESSIN

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

**Note** Not to be used in preference to enuresis alarms.

**Authority required (STREAMLINED)**

***5342***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)**

***5267***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12459R NP | ‡1 | 5 | .. | 120.11 | 30.00 | [a] Desmopressin Nasal Spray USP (Apotex) [DZ] |

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8712M NP | ‡1 | 5 | .. | 57.39 | 30.00 | [a] Minirin Nasal Spray [FP] |

# HYPOTHALAMIC HORMONES

*Gonadotropin-releasing hormones*

## ▪ NAFARELIN

**Restricted benefit**

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven.

**Restricted benefit**

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven, **AND**

- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
- Patient must have had a recent bone density assessment.

The date of the bone density assessment must be recorded in the patient's medical records.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

2962X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 123.83 | 30.00 | Synarel [PF] |

# CORTICOSTEROIDS FOR SYSTEMIC USE

## CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

*Mineralocorticoids*

### FLUDROCORTISONE

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

**fludrocortisone acetate 100 microgram tablet, 100**

1433K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 1 | .. | *34.67 | 30.00 | [a] Florinef [AS] | [a] FLUDROCORTISONE MEDSURGE [DZ] |

*Glucocorticoids*

### ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

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

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

13263C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 1359.77 | 30.00 | Yonsa Mpred [RA] |

### BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

5034Y

DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 29.15 | 30.00 | Celestone Chronodose [OQ] |

### BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

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

**Restricted benefit**

Alopecia areata
**Restricted benefit**
Local intra-articular or peri-articular infiltration
**Restricted benefit**
Granulomata
**Clinical criteria:**
- The condition must be dermal.

**Restricted benefit**
Keloid
**Restricted benefit**
Lichen planus hypertrophic
**Restricted benefit**
Lichen simplex chronicus
**Restricted benefit**
Chronic discoid lupus erythematosus
**Restricted benefit**
Necrobiosis lipoidica
**Restricted benefit**
Uveitis

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2694T NP | 1 | .. | .. | 29.15 | 30.00 | Celestone Chronodose [OQ] |

## ▪ CORTISONE

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

**cortisone acetate 25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1247P NP | 1 | 4 | .. | 25.45 | 26.85 | Cortate [AS] |

**cortisone acetate 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1246N NP | 1 | 4 | .. | 20.32 | 21.72 | Cortate [AS] |

## ▪ DEXAMETHASONE

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

**dexamethasone 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1292B NP | 1 | 4 | .. | 15.90 | 17.30 | Dexmethsone [AS] |

**dexamethasone 4 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2507Y NP | 1 | 4 | .. | 18.24 | 19.64 | Dexmethsone [AS] |

## ▪ HYDROCORTISONE

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

**hydrocortisone 20 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1500Y NP | 1 | 4 | .. | 33.63 | 30.00 | [a] Hydrocortisone Viatris 20 [AL] |
| | | | [B]3.00 | 36.63 | 30.00 | [a] Hysone 20 [AF] |

**hydrocortisone 4 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1499X NP | 1 | 4 | .. | 27.45 | 28.85 | [a] Hydrocortisone Viatris 4 [AL] |
| | | | [B]3.00 | 30.45 | 28.85 | [a] Hysone 4 [AF] |

## ▪ HYDROCORTISONE SODIUM SUCCINATE

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

1501B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *22.79 | 24.19 | Solu-Cortef [PF] |

NP

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

3096Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.75 | 23.15 | Solu-Cortef [PF] |

NP

## ▪ HYDROCORTISONE SODIUM SUCCINATE

**Restricted benefit**

For use in a hospital

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

1510L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *42.39 | 30.00 | Solu-Cortef [PF] |

NP

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

5118J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *42.39 | 30.00 | Solu-Cortef [PF] |

DP

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

1511M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *65.55 | 30.00 | Solu-Cortef [PF] |

NP

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

5119K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *65.55 | 30.00 | Solu-Cortef [PF] |

DP

## ▪ METHYLPREDNISOLONE

**methylprednisolone 1 g injection, 1 vial**

5264C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 45.49 | 30.00 | [a] Methylpred [AL] | [a] Methylprednisolone Alphapharm [AF] |
| | | | | | [a] Solu-Medrol [PF] | |

NP

## ▪ METHYLPREDNISOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

1928L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.37 | 25.77 | [a] Depo-Nisolone [FZ] |
| | | [B]2.61 | 26.98 | 25.77 | [a] Depo-Medrol [PF] |

NP

## ▪ METHYLPREDNISOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

5148Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.37 | 25.77 | [a] Depo-Nisolone [FZ] |
| | | [B]2.61 | 26.98 | 25.77 | [a] Depo-Medrol [PF] |

DP

## ▪ METHYLPREDNISOLONE

**Note** Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11739W NP | 5 | .. | .. | *42.57 | 30.00 | [a] Solu-Medrol [PF] |

**methylprednisolone 40 mg injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5263B NP | 1 | .. | .. | 25.13 | 26.53 | [a] Methylpred [AL] |

## ▪ PREDNISOLONE

**prednisolone 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3152X NP | 1 | 4 | .. | 16.28 | 17.68 | [a] Predsolone [LN] |
| | | | [B]0.93 | 17.21 | 17.68 | [a] Panafcortelone [AS] |

**prednisolone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1916W NP | 1 | 4 | .. | 17.38 | 18.78 | Panafcortelone [AS] | Solone [IL] |

**prednisolone 5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1917X NP | 1 | 4 | .. | 16.69 | 18.09 | Panafcortelone [AS] | Solone [IL] |

## ▪ PREDNISOLONE SODIUM PHOSPHATE

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8285C NP | ‡1 | 5 | .. | 19.38 | 20.78 | [a] PredMix [LN] |
| | | | [B]2.07 | 21.45 | 20.78 | [a] Redipred [AS] |

## ▪ PREDNISONE

**prednisone 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1934T NP | 1 | 4 | .. | 16.23 | 17.63 | [a] Predsone [LN] |
| | | | [B]0.93 | 17.16 | 17.63 | [a] Panafcort [AS] |

**prednisone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1936X NP | 1 | 4 | .. | 16.17 | 17.57 | Panafcort [AS] | Sone [IL] |

**prednisone 5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1935W NP | 1 | 4 | .. | 16.61 | 18.01 | Panafcort [AS] | Sone [IL] |

## ▪ TRIAMCINOLONE

**Restricted benefit**
Local intra-articular or peri-articular infiltration
**Restricted benefit**
Keloid
**Restricted benefit**
Lichen planus hypertrophic

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5233K DP | 1 | .. | .. | 29.15 | 30.00 | Kenacort-A10 [AS] |

## ▪ TRIAMCINOLONE

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

**Restricted benefit**
Alopecia areata
**Restricted benefit**
Local intra-articular or peri-articular infiltration
**Restricted benefit**
Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**
Keloid
**Restricted benefit**
Lichen planus hypertrophic
**Restricted benefit**
Lichen simplex chronicus
**Restricted benefit**
Chronic discoid lupus erythematosus
**Restricted benefit**
Necrobiosis lipoidica
**Restricted benefit**
Psoriasis

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2990J NP | 1 | .. | .. | 29.15 | 30.00 | Kenacort-A10 [AS] |

# THYROID THERAPY

## THYROID PREPARATIONS

*Thyroid hormones*

### LEVOTHYROXINE

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

**levothyroxine sodium 125 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12830G NP | 1 | 1 | .. | 26.42 | 27.82 | Eltroxin [LT] |

### LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 75 microgram tablet, 2 x 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12960D NP | 1 | 1 | .. | 23.26 | 24.66 | [a] LEVOXINE [RA] |

### LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 100 microgram tablet, 2 x 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12968M NP | 1 | 1 | .. | 23.45 | 24.85 | [a] LEVOXINE [RA] |

### LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 50 microgram tablet, 2 x 100**

12969N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 23.09 | 24.49 | [a] LEVOXINE [RA] |

## ▪ LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 200 microgram tablet, 2 x 100**

12970P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 25.26 | 26.66 | [a] LEVOXINE [RA] |

## ▪ LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 200 microgram tablet, 200**

2173J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 25.26 | 26.66 | [a] APO-Levothyroxine [XT]<br>[a] Levothyroxine Lup [GQ]<br>[b] Eltroxin [LT] | [a] Eutroxsig [LN]<br><br>[b] Levothox [AF] |
| | | [B]1.31 | 26.57 | 26.66 | [a] Oroxine [AS] | |

## ▪ LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 50 microgram tablet, 200**

2174K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 23.09 | 24.49 | [a] APO-Levothyroxine [XT]<br>[a] Levothyroxine Lup [GQ]<br>[b] Eltroxin [LT] | [a] Eutroxsig [LN]<br><br>[b] Levothox [AF] |
| | | [B]1.31 | 24.40 | 24.49 | [a] Oroxine [AS] | |

## ▪ LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 100 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2175L NP | 1 | 1 | .. | 23.45 | 24.85 | [a] APO-Levothyroxine [XT]<br>[a] Levothyroxine Lup [GQ]<br>[b] Eltroxin [LT] | [a] Eutroxsig [LN]<br><br>[b] Levothox [AF] |
| | | | [B]1.31 | 24.76 | 24.85 | [a] Oroxine [AS] | |

## ▪ LEVOTHYROXINE

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

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup or APO-Levothyroxine on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup and APO-Levothyroxine brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine brand) are equivalent for the purposes of substitution.

**levothyroxine sodium 75 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9287T NP | 1 | 1 | .. | 23.26 | 24.66 | [a] APO-Levothyroxine [XT]<br>[a] Levothyroxine Lup [GQ]<br>[b] Eltroxin [LT] | [a] Eutroxsig [LN]<br><br>[b] Levothox [AF] |
| | | | [B]1.32 | 24.58 | 24.66 | [a] Oroxine [AS] | |

## ▪ LIOTHYRONINE

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

**Authority required (STREAMLINED)**

***6382***
Thyroid cancer

**Authority required (STREAMLINED)**

***6410***
Hypothyroidism

**Clinical criteria:**

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

**Authority required (STREAMLINED)**

***6475***
Hypothyroidism

**Clinical criteria:**

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2318B NP | 1 | 2 | .. | 57.28 | 30.00 | Tertroxin [AS] |

## ANTITHYROID PREPARATIONS

*Thiouracils*

## ▪ PROPYLTHIOURACIL

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

**propylthiouracil 50 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1955X NP | 2 | 2 | .. | *44.45 | 30.00 | PTU [FF] |

*Sulfur-containing imidazole derivatives*

## ▪ CARBIMAZOLE

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

**carbimazole 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1153Q NP | 2 | 2 | .. | *33.67 | 30.00 | [a] Neo-Mercazole [GH] | [a] WP Carbimazole [TN] |

# ▪ PANCREATIC HORMONES

## GLYCOGENOLYTIC HORMONES

*Glycogenolytic hormones*

## ▪ GLUCAGON HYDROCHLORIDE

**Note** Pharmaceutical Benefits that have the form glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack are equivalent for the purpose of substitution in case of a shortage.

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13612K DP | 1 | .. | .. | 91.98 | 30.00 | [a] GlucaGen Hypokit (Germany) [DZ] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13614M NP | 1 | 1 | .. | 91.98 | 30.00 | [a] GlucaGen Hypokit (Germany) [DZ] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1449G NP | 1 | 1 | .. | 50.63 | 30.00 | [a] GlucaGen Hypokit [NO] |

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

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5105Q DP | 1 | .. | .. | 50.63 | 30.00 | [a] GlucaGen Hypokit [NO] |

# ▪ CALCIUM HOMEOSTASIS

## PARATHYROID HORMONES AND ANALOGUES

*Parathyroid hormones and analogues*

## ▪ TERIPARATIDE

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

**Authority required (STREAMLINED)**
***12492***
Severe established osteoporosis
Treatment Phase: Initial treatment
**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority required (STREAMLINED)**

***12270***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

12670W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 176.83 | 30.00 | Terrosa [FX] |

## ANTI-PARATHYROID AGENTS

*Calcitonin preparations*

### ▪ CALCITONIN SALMON

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

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

**Authority required**

Symptomatic Paget disease of bone

**Clinical criteria:**

- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**Authority required**

Hypercalcaemia

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**calcitonin salmon 100 units/mL injection, 5 x 1 mL ampoules**

2997R

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *127.92 | 30.00 | Miacalcic 100 [EU] |

*Other anti-parathyroid agents*

### ▪ CINACALCET

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

**Authority required (STREAMLINED)**

***10068***

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; OR
- Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

**cinacalcet 30 mg tablet, 28**

| 9157Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 43.04 | 30.00 | [a] Cinacalcet Mylan [AF]<br>[a] Pharmacor Cinacalcet [CR] | [a] Cinacalcet Viatris [AL] |

**cinacalcet 60 mg tablet, 28**

| 9158B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 73.10 | 30.00 | [a] Cinacalcet Mylan [AF]<br>[a] Pharmacor Cinacalcet [CR] | [a] Cinacalcet Viatris [AL] |

**cinacalcet 90 mg tablet, 28**

| 9159C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 103.16 | 30.00 | [a] Cinacalcet Mylan [AF]<br>[a] Pharmacor Cinacalcet [CR] | [a] Cinacalcet Viatris [AL] |

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### TETRACYCLINES

*Tetracyclines*

### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**doxycycline 100 mg tablet, 7**

| 2709N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 15.68 | 17.08 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 7**

| 3321T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.68 | 17.08 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 7**

| 5082L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.68 | 17.08 | [a] APO-Doxycycline [TX] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg tablet, 7**

| 9105F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 15.68 | 17.08 | [a] APO-Doxycycline [TX] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg modified release capsule, 7**

| 2708M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | [B]1.54 | 17.22 | 17.08 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]2.95 | 18.63 | 17.08 | [a] Doryx [YN] |

**doxycycline 100 mg modified release capsule, 7**

| 3322W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | [B]1.54 | 17.22 | 17.08 | [a] Mayne Pharma Doxycycline [YT] |
| | | | [B]2.95 | 18.63 | 17.08 | [a] Doryx [YN] |

### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Urethritis

**doxycycline 100 mg tablet, 7**

2714W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *21.06 | 22.46 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 7**

9108J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *21.06 | 22.46 | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg tablet, 21**

10176N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 21.05 | 22.45 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 21**

1800R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.05 | 22.45 | [a] APO-Doxycycline [TX] |

**doxycycline 100 mg modified release capsule, 21**

2715X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | [B]3.22 | 24.27 | 22.45 | [a] Mayne Pharma Doxycycline [YT] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Severe acne

**doxycycline 100 mg tablet, 7**

10779H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | .. | *23.77 | 25.17 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 7**

10781K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | .. | *23.77 | 25.17 | [a] APO-Doxycycline [TX] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg modified release capsule, 7**

10777F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | [B]6.16 | *29.93 | 25.17 | [a] Mayne Pharma Doxycycline [YT] |
| | | [B]11.80 | *35.57 | 25.17 | [a] Doryx [YN] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Pelvic inflammatory disease

**doxycycline 100 mg tablet, 7**

2702F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | .. | .. | *23.77 | 25.17 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 100 [AF] | [a] Doxsig [RW] |

**doxycycline 100 mg tablet, 7**

9107H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | .. | .. | *23.77 | 25.17 | [a] APO-Doxycycline [TX] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg modified release capsule, 7**

2703G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | [B]6.16 | *29.93 | 25.17 | [a] Mayne Pharma Doxycycline [YT] |
| | | [B]11.80 | *35.57 | 25.17 | [a] Doryx [YN] |

## ▪ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Bronchiectasis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Chronic bronchitis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Severe acne

### doxycycline 50 mg tablet, 25

2711Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.07 | 17.47 | [a] APX-Doxycycline [TX]<br>[a] Doxylin 50 [AF] | [a] Doxsig [RW] |

### doxycycline 50 mg tablet, 25

9106G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.07 | 17.47 | [a] APO-Doxycycline [TX] | [a] Doxycycline Sandoz [HX] |

### doxycycline 50 mg modified release capsule, 25

2707L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | [B]2.41 | 18.48 | 17.47 | [a] Mayne Pharma Doxycycline [YT] |
| | | [B]4.80 | 20.87 | 17.47 | [a] Doryx [YN] |

## ▪ MINOCYCLINE

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

### minocycline 50 mg tablet, 60

1616C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 22.14 | 23.54 | [a] Akamin 50 [AF] | [a] Minomycin-50 [AS] |

## BETA-LACTAM ANTIBACTERIALS, PENICILLINS

*Penicillins with extended spectrum*

## ▪ AMOXICILLIN

### amoxicillin 250 mg capsule, 20

3301R (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] Alphamox 250 [AF]<br>[a] APO-Amoxycillin [TX] | [a] AMILOXYN [RF]<br>[a] Cilamox [AL] |
| | | [B]4.68 | 20.38 | 17.10 | [a] Amoxil [AS] | |

### amoxicillin 500 mg capsule, 20

3300Q (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] Alphamox 500 [AF]<br>[a] Amoxycillin generichealth 500 [GQ]<br>[a] APO-Amoxycillin [TX]<br>[a] NOUMED AMOXICILLIN [VO] | [a] AMILOXYN [RF]<br>[a] Amoxycillin Sandoz [SZ]<br>[a] Cilamox [AL] |
| | | [B]4.67 | 20.37 | 17.10 | [a] Amoxil [AS] | |

### amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

5225B (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #19.23 | 21.03 | Maxamox [SZ] |

### amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

8705E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | #19.23 | 21.03 | Maxamox [SZ] |

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1888J NP | ‡1 | 1 | [S]0.53 | #22.90 | 24.17 | Amoxil [AS] |

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3310F DP | ‡1 | .. | [S]0.53 | #22.90 | 24.17 | Amoxil [AS] |

**amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1886G NP | ‡1 | 1 | .. | #18.96 | 20.76 | [a] APO-Amoxycillin [TX] | [a] NOUMED AMOXICILLIN [VO] |
| | | | [B]4.55 | #23.51 | 20.76 | [a] Amoxil [AS] | |

**amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3302T DP | ‡1 | .. | .. | #18.96 | 20.76 | [a] APO-Amoxycillin [TX] | [a] NOUMED AMOXICILLIN [VO] |
| | | | [B]4.55 | #23.51 | 20.76 | [a] Amoxil [AS] | |

## ▪ AMOXICILLIN

**Authority required (STREAMLINED)**

***10416***

Community acquired pneumonia

**Clinical criteria:**

- Patient must have community acquired pneumonia.

**amoxicillin 1 g tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12002Q NP | 1 | 1 | .. | 15.90 | 17.30 | [a] Amoxycillin Sandoz [BG] |
| | | | [B]1.00 | 16.90 | 17.30 | [a] Maxamox [SZ] |

## ▪ AMOXICILLIN

**Note** Pharmaceutical benefits that have the form amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL are equivalent for the purposes of substitution in the case of a shortage.

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13182T NP | ‡1 | 1 | .. | #37.93 | 30.00 | [a] Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent) [RQ] |

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13184X DP | ‡1 | .. | .. | #37.93 | 30.00 | [a] Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent) [RQ] |

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1887H NP | ‡1 | 1 | .. | #18.96 | 20.76 | [a] Amoxycillin Sandoz [SZ]<br>[a] Cilamox [AL] | [a] APO-Amoxycillin [TX]<br>[a] NOUMED AMOXICILLIN [VO] |
| | | | [B]4.32 | #23.28 | 20.76 | [a] Amoxil Forte [AS] | |

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3393N DP | ‡1 | .. | .. | #18.96 | 20.76 | [a] Amoxycillin Sandoz [SZ]<br>[a] Cilamox [AL] | [a] APO-Amoxycillin [TX]<br>[a] NOUMED AMOXICILLIN [VO] |
| | | | [B]4.32 | #23.28 | 20.76 | [a] Amoxil Forte [AS] | |

## ▪ AMOXICILLIN

**Restricted benefit**

Chronic bronchitis

**Clinical criteria:**

- Patient must have acute exacerbations of the condition.

**amoxicillin 1 g tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8581P NP | 1 | 1 | .. | 15.90 | 17.30 | [a] Amoxycillin Sandoz [BG] |
| | | | [B]1.00 | 16.90 | 17.30 | [a] Maxamox [SZ] |

## ▪ AMOXICILLIN

**Authority required**

Infection suspected or proven to be due to a susceptible organism

**Clinical criteria:**

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

9714G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | #22.90 | 24.70 | Amoxil [AS] |

## ▪ AMOXICILLIN

**Authority required (STREAMLINED)**

***10402***

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; OR
- Patient must have pyelonephritis; OR
- Patient must have a tooth avulsion; OR
- Patient must have salmonella enteritis; OR
- Patient must have community acquired pneumonia; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 500 mg capsule, 20**

11947T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | [a] Alphamox 500 [AF] | [a] AMILOXYN [RF] |
| | | | | | [a] Amoxycillin generichealth 500 [GQ] | [a] Amoxycillin Sandoz [SZ] |
| | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |
| | | | | | [a] NOUMED AMOXICILLIN [VO] | |
| | | [B]9.34 | *27.75 | 19.81 | [a] Amoxil [AS] | |

## ▪ AMOXICILLIN

**Authority required (STREAMLINED)**

***10404***

Infection

**Clinical criteria:**

- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 250 mg capsule, 20**

11998L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | [a] Alphamox 250 [AF] | [a] AMILOXYN [RF] |
| | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |
| | | [B]9.36 | *27.77 | 19.81 | [a] Amoxil [AS] | |

## ▪ AMOXICILLIN

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

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

**amoxicillin 250 mg capsule, 20**

1884E NP MW

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] Alphamox 250 [AF] | [a] AMILOXYN [RF] |
| | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |
| | | [B]4.68 | 20.38 | 17.10 | [a] Amoxil [AS] | |

**amoxicillin 500 mg capsule, 20**

1889K NP MW

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] Alphamox 500 [AF] | [a] AMILOXYN [RF] |
| | | | | | [a] Amoxycillin generichealth 500 [GQ] | [a] Amoxycillin Sandoz [SZ] |
| | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |
| | | | | | [a] NOUMED AMOXICILLIN [VO] | |
| | | [B]4.67 | 20.37 | 17.10 | [a] Amoxil [AS] | |

*Beta-lactamase sensitive penicillins*

## ▪ BENZATHINE BENZYLPENICILLIN

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

2267H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 305.73 | 30.00 | Bicillin L-A [PF] |

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

5027N DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 305.73 | 30.00 | Bicillin L-A [PF] |

**benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11723B NP | 1 | .. | .. | 156.87 | 30.00 | Bicillin L-A [PF] |

**benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11735P DP | 1 | .. | .. | 156.87 | 30.00 | Bicillin L-A [PF] |

## ▪ BENZYLPENICILLIN

**benzylpenicillin 3 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2647H NP | 10 | .. | .. | *108.77 | 30.00 | BenPen [CS] |

**benzylpenicillin 3 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3399X DP | 10 | .. | .. | *108.77 | 30.00 | BenPen [CS] |

**benzylpenicillin 600 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1775K NP MW | 10 | 1 | .. | *72.37 | 30.00 | BenPen [CS] |

**benzylpenicillin 600 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3398W DP | 10 | .. | .. | *72.37 | 30.00 | BenPen [CS] |

## ▪ PHENOXYMETHYLPENICILLIN

**phenoxymethylpenicillin 500 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3028J NP | 2 | .. | .. | *20.37 | 21.77 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 500 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3361X DP | 2 | .. | .. | *20.37 | 21.77 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1789E NP | 1 | .. | .. | 17.23 | 18.63 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3363B DP | 1 | .. | .. | 17.23 | 18.63 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2965C NP | 1 | .. | .. | 18.45 | 19.85 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3364C DP | 1 | .. | .. | 18.45 | 19.85 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5012T DP | 2 | .. | .. | *24.69 | 26.09 | Cilicaine V [AF] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9143F NP | 2 | 1 | .. | *24.69 | 26.09 | Cilicaine V [AF] |

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5024K DP | 2 | .. | .. | *#23.57 | 25.37 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8976K NP | 2 | 1 | .. | *#23.57 | 25.37 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 250 mg tablet, 25**

1787C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | Aspecillin VK [AF] |

NP

**phenoxymethylpenicillin 250 mg tablet, 25**

3360W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | Aspecillin VK [AF] |

DP

## ▪ PHENOXYMETHYLPENICILLIN

**Note** Pharmaceutical Benefits that have the form phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL are equivalent for the purpose of substitution in case of a shortage.

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

13282C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *#69.81 | 30.00 | [a] Penopen [QY] |

NP

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

13291M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *#69.81 | 30.00 | [a] Penopen [QY] |

DP

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

5029Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *#25.03 | 26.83 | [a] Phenoxymethylpenicillin-AFT [AE] |

DP

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

8977L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *#25.03 | 26.83 | [a] Phenoxymethylpenicillin-AFT [AE] |

NP

## ▪ PHENOXYMETHYLPENICILLIN

**Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg capsule, 50**

1705R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.23 | 18.63 | Cilicaine VK [AF] | LPV [IL] |

NP

**phenoxymethylpenicillin 250 mg tablet, 25**

1703P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | Aspecillin VK [AF] |

NP

## ▪ PROCAINE BENZYLPENICILLIN

**procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes**

1794K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 62.27 | 30.00 | Cilicaine [AF] |

NP

**procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes**

3371K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 62.27 | 30.00 | Cilicaine [AF] |

DP

*Beta-lactamase resistant penicillins*

## ▪ DICLOXACILLIN

**Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

5096F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 17.70 | 19.10 | [a] Dicloxacillin Mylan 250 [AL] |
| | | [B]1.86 | 19.56 | 19.10 | [a] Distaph 250 [AF] |

DP

**dicloxacillin 500 mg capsule, 24**

5097G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.09 | 22.49 | [a] Dicloxacillin Mylan 500 [AL] |
| | | [B]1.95 | 23.04 | 22.49 | [a] Distaph 500 [AF] |

DP

## ▪ DICLOXACILLIN

**Restricted benefit**

Serious staphylococcal infection

### dicloxacillin 250 mg capsule, 24

8121K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 17.70 | 19.10 | [a] Dicloxacillin Mylan 250 [AL] |
| | | [B]1.86 | 19.56 | 19.10 | [a] Distaph 250 [AF] |

NP MW

### dicloxacillin 500 mg capsule, 24

8122L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.09 | 22.49 | [a] Dicloxacillin Mylan 500 [AL] |
| | | [B]1.95 | 23.04 | 22.49 | [a] Distaph 500 [AF] |

NP MW

## ▪ DICLOXACILLIN

**Authority required (STREAMLINED)**

***6188***

Osteomyelitis

### dicloxacillin 500 mg capsule, 24

10790X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *29.19 | 30.00 | [a] Dicloxacillin Mylan 500 [AL] |
| | | [B]3.90 | *33.09 | 30.00 | [a] Distaph 500 [AF] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

### flucloxacillin 1 g injection, 5 vials

1525G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 22.13 | 23.53 | Flucil [AS] |

NP

### flucloxacillin 1 g injection, 5 vials

5095E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 22.13 | 23.53 | Flucil [AS] |

DP

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

### flucloxacillin 250 mg capsule, 24

1526H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.26 | 18.66 | [a] APO-Flucloxacillin [TX] | [a] Flopen [AL] |
| | | | | | [a] Flopen Viatris [MQ] | [a] Staphylex 250 [AF] |

NP MW

### flucloxacillin 500 mg capsule, 24

1527J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 21.68 | 23.08 | [a] APO-Flucloxacillin [TX] | [a] Flopen [AL] |
| | | | | | [a] Flopen Viatris [MQ] | [a] Staphylex 500 [AF] |

NP MW

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

### flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

5257Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #22.99 | 24.79 | Flucil [LN] |

DP

### flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

5258R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #25.83 | 27.63 | Flucil [LN] |

DP

### flucloxacillin 250 mg capsule, 24

5090X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.26 | 18.66 | [a] APO-Flucloxacillin [TX] | [a] Flopen [AL] |
| | | | | | [a] Flopen Viatris [MQ] | [a] Staphylex 250 [AF] |

DP

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5091Y DP | 1 | .. | .. | 21.68 | 23.08 | [a] APO-Flucloxacillin [TX]<br>[a] Flopen Viatris [MQ] | [a] Flopen [AL]<br>[a] Staphylex 500 [AF] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9149M NP | ‡1 | 1 | .. | #22.99 | 24.79 | Flucil [LN] |

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9150N NP | ‡1 | 1 | .. | #25.83 | 27.63 | Flucil [LN] |

## ▪ FLUCLOXACILLIN

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority required (STREAMLINED)**

***6169***

Osteomyelitis

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10788T | 2 | 1 | .. | *30.37 | 30.00 | [a] APO-Flucloxacillin [TX]<br>[a] Flopen Viatris [MQ] | [a] Flopen [AL]<br>[a] Staphylex 500 [AF] |

*Combinations of penicillins, incl. beta-lactamase inhibitors*

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Authority required (STREAMLINED)**

***10405***

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11941L NP | 2 | .. | .. | *19.01 | 20.41 | [a] AlphaClav Duo [AF]<br>[a] AMCLAVOX DUO 500/125 [RW]<br>[a] Amoxyclav AN 500/125 [EA]<br>[a] APO-AMOXY/CLAV 500/125 [TW]<br>[a] Curam Duo 500/125 [SZ] | [a] Alphaclav Duo Viatris [AL]<br>[a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY]<br>[a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]<br>[a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | [B]10.82 | *29.83 | 20.41 | [a] Augmentin Duo [AS] | |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Note** Pharmaceutical benefits that have the form amoxicillin 875 mg + clavulanic acid 125 mg tablet in a pack size of 10 can be substituted for a pack size of 20 in the case of a shortage.

**Authority required (STREAMLINED)**

***10413***

Infection

**Clinical criteria:**

- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have postpartum endometritis; OR
- Patient must have an exacerbation of bronchiectasis; OR
- Patient must have pyelonephritis; OR
- Patient must have pneumonia acquired in hospital or aged care; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20**

| 13194K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 53.82 | 30.00 | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) [DZ] | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) [QY] |
| | | | | | | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) [QZ] | |

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

| 11933C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *19.61 | 21.01 | [a] AlphaClav Duo Forte [AF] | [a] Alphaclav Duo Forte Viatris [AL] |
| | | | | | | [a] AMCLAVOX DUO FORTE 875/125 [RW] | [a] Amoxyclav AN 875/125 [EA] |
| | | | | | | [a] AmoxyClav generichealth 875/125 [HQ] | [a] APO-Amoxycillin and Clavulanic Acid [TX] |
| | | | | | | [a] APO-AMOXY/CLAV 875/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | | [a] Curam Duo Forte 875/125 [SZ] | |
| | | | [B]13.56 | *33.17 | 21.01 | [a] Augmentin Duo forte [AS] | |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

| 8319W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #18.96 | 20.76 | [a] Curam Duo [SZ] |
| | | | [B]5.26 | #24.22 | 20.76 | [a] Augmentin Duo 400 [AS] |

**amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

| 1892N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #18.96 | 20.76 | Curam [SZ] |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

| 5011R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #18.96 | 20.76 | [a] Curam Duo [SZ] |
| | | | [B]5.26 | #24.22 | 20.76 | [a] Augmentin Duo 400 [AS] |

**amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

| 5009P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #18.96 | 20.76 | Curam [SZ] |

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

| 5008N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 16.00 | 17.40 | [a] AlphaClav Duo [AF] | [a] Alphaclav Duo Viatris [AL] |
| | | | | | | [a] AMCLAVOX DUO 500/125 [RW] | [a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY] |
| | | | | | | [a] Amoxyclav AN 500/125 [EA] | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] |
| | | | | | | [a] APO-AMOXY/CLAV 500/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | | [a] Curam Duo 500/125 [SZ] | |
| | | | [B]5.41 | 21.41 | 17.40 | [a] Augmentin Duo [AS] | |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Note** Pharmaceutical benefits that have the form amoxicillin 875 mg + clavulanic acid 125 mg tablet in a pack size of 10 can be substituted for a pack size of 20 in the case of a shortage.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20**

13190F (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *39.80 | 30.00 | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) [DZ]<br>[a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) [QZ] | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) [QY] |

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

5006L (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.30 | 17.70 | [a] AlphaClav Duo Forte [AF] | [a] Alphaclav Duo Forte Viatris [AL] |
| | | | | | [a] AMCLAVOX DUO FORTE 875/125 [RW] | [a] Amoxyclav AN 875/125 [EA] |
| | | | | | [a] AmoxyClav generichealth 875/125 [HQ] | [a] APO-Amoxycillin and Clavulanic Acid [TX] |
| | | | | | [a] APO-AMOXY/CLAV 875/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | [a] Curam Duo Forte 875/125 [SZ] | |
| | | [B]6.78 | 23.08 | 17.70 | [a] Augmentin Duo forte [AS] | |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

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

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

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

1891M (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.00 | 17.40 | [a] AlphaClav Duo [AF] | [a] Alphaclav Duo Viatris [AL] |
| | | | | | [a] AMCLAVOX DUO 500/125 [RW] | [a] Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY] |
| | | | | | [a] Amoxyclav AN 500/125 [EA] | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] |
| | | | | | [a] APO-AMOXY/CLAV 500/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | [a] Curam Duo 500/125 [SZ] | |
| | | [B]5.41 | 21.41 | 17.40 | [a] Augmentin Duo [AS] | |

## ▪ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Note** Pharmaceutical benefits that have the form amoxicillin 875 mg + clavulanic acid 125 mg tablet in a pack size of 10 can be substituted for a pack size of 20 in the case of a shortage.

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

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

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20**

13179P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *39.80 | 30.00 | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge) [DZ]<br>[a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) [QZ] | [a] Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals) [QY] |

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

8254K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.30 | 17.70 | [a] AlphaClav Duo Forte [AF] | [a] Alphaclav Duo Forte Viatris [AL] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] AMCLAVOX DUO FORTE 875/125 [RW] | [a] Amoxyclav AN 875/125 [EA] |
| | | | | | [a] AmoxyClav generichealth 875/125 [HQ] | [a] APO-Amoxycillin and Clavulanic Acid [TX] |
| | | | | | [a] APO-AMOXY/CLAV 875/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | [a] Curam Duo Forte 875/125 [SZ] | |
| | [B]6.78 | 23.08 | 17.70 | | [a] Augmentin Duo forte [AS] | |

## OTHER BETA-LACTAM ANTIBACTERIALS

*First-generation cephalosporins*

### ▪ CEFALEXIN

**cefalexin 250 mg capsule, 20**

| 3317N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.70 | 17.10 | [a] APO-Cephalexin [TX] | [a] Ibilex 250 [AF] |
| | | | [B]4.72 | 20.42 | 17.10 | [a] Keflex [AS] | |

**cefalexin 500 mg capsule, 20**

| 3318P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.70 | 17.10 | [a] APO-Cephalexin [TX] | [a] Cefalexin Sandoz [SZ] |
| | | | | | | [a] Cephalex 500 [CR] | [a] Cephalexin generichealth [GQ] |
| | | | | | | [a] Ibilex 500 [AF] | [a] NOUMED CEFALEXIN [VO] |
| | | | [B]6.28 | 21.98 | 17.10 | [a] Keflex [AS] | |

**cefalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3094W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #18.96 | 20.76 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 125 [AF] |
| | | | [B]4.66 | #23.62 | 20.76 | [a] Keflex [AS] | |

**cefalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3319Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #18.96 | 20.76 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 125 [AF] |
| | | | [B]4.66 | #23.62 | 20.76 | [a] Keflex [AS] | |

### ▪ CEFALEXIN

**Note** Pharmaceutical Benefits that have the form cefalexin 250 mg/5 mL powder for oral liquid, 100 mL are equivalent for the purpose of substitution in case of a shortage.

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 13278W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #36.48 | 30.00 | [a] Keforal [QY] |

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 13285F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #36.48 | 30.00 | [a] Keforal [QY] |

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3095X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | .. | #19.06 | 20.86 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 250 [AF] |
| | | | [B]6.01 | #25.07 | 20.86 | [a] Keflex [AS] | |

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3320R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | .. | .. | #19.06 | 20.86 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 250 [AF] |
| | | | [B]6.01 | #25.07 | 20.86 | [a] Keflex [AS] | |

### ▪ CEFALEXIN

**Authority required (STREAMLINED)**

***6188***

Osteomyelitis

**cefalexin 500 mg capsule, 20**

| 10778G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 1 | .. | *18.41 | 19.81 | [a] APO-Cephalexin [TX] | [a] Cefalexin Sandoz [SZ] |
| | | | | | | [a] Cephalex 500 [CR] | [a] Cephalexin generichealth [GQ] |
| | | | | | | [a] Ibilex 500 [AF] | [a] NOUMED CEFALEXIN [VO] |
| | | | [B]12.56 | *30.97 | 19.81 | [a] Keflex [AS] | |

### ▪ CEFALEXIN

**Authority required (STREAMLINED)**

***10410***
Infection
**Clinical criteria:**

- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only.

**cefalexin 500 mg capsule, 20**

11934D (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | [a] APO-Cephalexin [TX] | [a] Cefalexin Sandoz [SZ] |
| | | | | | [a] Cephalex 500 [CR] | [a] Cephalexin generichealth [GQ] |
| | | | | | [a] Ibilex 500 [AF] | [a] NOUMED CEFALEXIN [VO] |
| | | [B]12.56 | *30.97 | 19.81 | [a] Keflex [AS] | |

## ▪ CEFALEXIN

**Authority required (STREAMLINED)**
***10412***
Infection
**Clinical criteria:**

- Patient must have impaired renal function, **AND**
- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.

**cefalexin 250 mg capsule, 20**

11963P (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | [a] APO-Cephalexin [TX] | [a] Ibilex 250 [AF] |
| | | [B]9.44 | *27.85 | 19.81 | [a] Keflex [AS] | |

## ▪ CEFALEXIN

**Authority required (STREAMLINED)**
***4243***
Prophylaxis of urinary tract infection

**cefalexin 250 mg capsule, 20**

2655R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | .. | *18.41 | 19.81 | [a] APO-Cephalexin [TX] | [a] Ibilex 250 [AF] |
| | | [B]9.44 | *27.85 | 19.81 | [a] Keflex [AS] | |

## ▪ CEFALEXIN

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

**cefalexin 250 mg capsule, 20**

3058Y (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] APO-Cephalexin [TX] | [a] Ibilex 250 [AF] |
| | | [B]4.72 | 20.42 | 17.10 | [a] Keflex [AS] | |

**cefalexin 500 mg capsule, 20**

3119E (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] APO-Cephalexin [TX] | [a] Cefalexin Sandoz [SZ] |
| | | | | | [a] Cephalex 500 [CR] | [a] Cephalexin generichealth [GQ] |
| | | | | | [a] Ibilex 500 [AF] | [a] NOUMED CEFALEXIN [VO] |
| | | [B]6.28 | 21.98 | 17.10 | [a] Keflex [AS] | |

## ▪ CEFAZOLIN

**Restricted benefit**

Cellulitis

**cefazolin 1 g injection, 5 vials**

1799Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *21.59 | 22.99 | Cefazolin-AFT [AE] |

## ▪ CEFAZOLIN

**Restricted benefit**

Cellulitis

**cefazolin 500 mg injection, 5 vials**

5477G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *20.37 | 21.77 | Cefazolin-AFT [AE] |

## ▪ CEFAZOLIN

**Note** Pharmaceutical benefits that have the form cefazolin 2 g injection, 5 vials, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials are equivalent for the purposes of substitution.

**Restricted benefit**

Cellulitis

**cefazolin 2 g injection, 5 vials**

13080K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *46.21 | 30.00 | [a] Cefazolin-AFT [AE] |

**cefazolin 2 g injection, 10 vials**

12115P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 46.21 | 30.00 | [a] Cephazolin Alphapharm [AF] | [a] Cephazolin Viatris [AL] |

## ▪ CEFAZOLIN

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**cefazolin 500 mg injection, 5 vials**

1256D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *20.37 | 21.77 | Cefazolin-AFT [AE] |

## ▪ CEFAZOLIN

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**cefazolin 1 g injection, 5 vials**

1797N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *21.59 | 22.99 | Cefazolin-AFT [AE] |

## ▪ CEFAZOLIN

**Note** Pharmaceutical benefits that have the form cefazolin 2 g injection, 5 vials, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

**cefazolin 2 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13097H NP | 2 | .. | .. | *46.21 | 30.00 | [a] Cefazolin-AFT [AE] |

**cefazolin 2 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12118T NP | 1 | .. | .. | 46.21 | 30.00 | [a] Cephazolin Alphapharm [AF] | [a] Cephazolin Viatris [AL] |

*Second-generation cephalosporins*

## ▪ CEFACLOR

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2460L | ‡1 | 1 | .. | #19.96 | 21.76 | [a] Aclor 125 [MQ] | [a] Keflor [AF] |
| | | | [B]7.85 | #27.81 | 21.76 | [a] Ceclor [AL] | |

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5046N DP | ‡1 | .. | .. | #19.96 | 21.76 | [a] Aclor 125 [MQ] | [a] Keflor [AF] |
| | | | [B]7.85 | #27.81 | 21.76 | [a] Ceclor [AL] | |

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2461M | ‡1 | 1 | .. | #19.96 | 21.76 | [a] Aclor 250 [MQ]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |
| | | | [B]7.85 | #27.81 | 21.76 | [a] Ceclor [AL] | |

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5047P DP | ‡1 | .. | .. | #19.96 | 21.76 | [a] Aclor 250 [MQ]<br>[a] Keflor [AF] | [a] APO-Cefaclor [TX] |
| | | | [B]7.85 | #27.81 | 21.76 | [a] Ceclor [AL] | |

**cefaclor 375 mg modified release tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1169M | 1 | 1 | .. | 16.90 | 18.30 | [a] APO-Cefaclor CD [TX]<br>[a] Keflor CD [AF] | [a] Karlor CD [MQ] |
| | | | [B]7.85 | 24.75 | 18.30 | [a] Ceclor CD [AL] | |

**cefaclor 375 mg modified release tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5045M DP | 1 | .. | .. | 16.90 | 18.30 | [a] APO-Cefaclor CD [TX]<br>[a] Keflor CD [AF] | [a] Karlor CD [MQ] |
| | | | [B]7.85 | 24.75 | 18.30 | [a] Ceclor CD [AL] | |

## ▪ CEFUROXIME

**cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11191B DP | ‡1 | .. | .. | #28.34 | 30.00 | Zinnat [AS] |

**cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11192C | ‡1 | 1 | .. | #28.34 | 30.00 | Zinnat [AS] |

**cefuroxime 250 mg tablet, 20**

11227X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 23.38 | 24.78 | [a] Pharmacor Cefuroxime [CR] |
| | | [B]3.00 | 26.38 | 24.78 | [a] Zinnat [AS] |

**cefuroxime 250 mg tablet, 20**

11228Y

DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 23.38 | 24.78 | [a] Pharmacor Cefuroxime [CR] |
| | | [B]3.00 | 26.38 | 24.78 | [a] Zinnat [AS] |

**cefuroxime 250 mg tablet, 14**

5052X

DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 20.26 | 21.66 | Pharmacor Cefuroxime [CR] |

**cefuroxime 250 mg tablet, 14**

8292K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 20.26 | 21.66 | Pharmacor Cefuroxime [CR] |

*Third-generation cephalosporins*

## ▪ CEFOTAXIME

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**cefotaxime 1 g injection, 10 vials**

1768C

DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 35.04 | 30.00 | DBL Cefotaxime [PF] |

## ▪ CEFOTAXIME

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**cefotaxime 1 g injection, 10 vials**

1758M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 35.04 | 30.00 | DBL Cefotaxime [PF] |

## ▪ CEFTRIAXONE

**Restricted benefit**

Gonorrhoea

**ceftriaxone 500 mg injection, 1 vial**

9058R

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 15.68 | 17.08 | Ceftriaxone-AFT [AE] |

## ▪ CEFTRIAXONE

**Note Shared Care Model**:

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

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**ceftriaxone 500 mg injection, 1 vial**

1783W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *26.42 | 27.82 | Ceftriaxone-AFT [AE] |

## ▪ CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 1 g injection, 1 vial, pharmaceutical benefits that have the form ceftriaxone 1 g injection, 5 vials, and pharmaceutical benefits that have the form ceftriaxone 1 g injection, 10 vials are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

### ceftriaxone 1 g injection, 10 vials

12114N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *32.10 | 30.00 | [a] Ceftriaxone Alphapharm [AF] | [a] Ceftriaxone Viatris [AL] |

### ceftriaxone 1 g injection, 1 vial

1784X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *26.67 | 28.07 | [a] Ceftriaxone-AFT [AE] |

### ceftriaxone 1 g injection, 5 vials

1788D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 26.70 | 28.10 | [a] Ceftriaxone Alphapharm [AF] | [a] Ceftriaxone Viatris [AL] |

## ▪ CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial, pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials, and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

### ceftriaxone 2 g injection, 5 vials

11169W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 26.81 | 28.21 | [a] Ceftriaxone Alphapharm [AF] | [a] Ceftriaxone Viatris [AL] |

### ceftriaxone 2 g injection, 10 vials

12112L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *32.23 | 30.00 | [a] Ceftriaxone Alphapharm [AF] | [a] Ceftriaxone Viatris [AL] |

### ceftriaxone 2 g injection, 1 vial

1785Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *26.77 | 28.17 | [a] Ceftriaxone-AFT [AE] |

*Fourth-generation cephalosporins*

## ▪ CEFEPIME

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

**Authority required**
Febrile neutropenia

### cefepime 1 g injection, 1 vial

8315P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10 | .. | .. | *53.07 | 30.00 | [a] Cefepime-AFT [AE]<br>[a] Cefepime Kabi [PK] | [a] Cefepime Alphapharm [AF]<br>[a] Omegapharm Pty Ltd [OE] |

**cefepime 2 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8316Q NP | 10 | .. | .. | *68.87 | 30.00 | [a] Cefepime-AFT [AE] | [a] Cefepime Alphapharm [AF] |
| | | | | | | [a] Cefepime Kabi [PK] | [a] Omegapharm Pty Ltd [OE] |

## SULFONAMIDES AND TRIMETHOPRIM

*Trimethoprim and derivatives*

### ▪ TRIMETHOPRIM

**trimethoprim 300 mg tablet, 7**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2922T NP | 1 | 1 | .. | 15.68 | 17.08 | [a] Trimethoprim Mylan [AL] | [a] Trimethoprim Viatris [MQ] |
| | | | [B]2.76 | 18.44 | 17.08 | [a] Alprim [AF] | |
| | | | [B]3.98 | 19.66 | 17.08 | [a] Triprim [RW] | |

### ▪ TRIMETHOPRIM

**Authority required (STREAMLINED)**

***4243***

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2666H | 2 | 2 | .. | *18.37 | 19.77 | [a] Trimethoprim Mylan [AL] | [a] Trimethoprim Viatris [MQ] |
| | | | [B]5.52 | *23.89 | 19.77 | [a] Alprim [AF] | |
| | | | [B]7.96 | *26.33 | 19.77 | [a] Triprim [RW] | |

### ▪ TRIMETHOPRIM

**Restricted benefit**

Prostatitis

**trimethoprim 300 mg tablet, 7**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10785P | 4 | .. | .. | *23.77 | 25.17 | [a] Trimethoprim Mylan [AL] | [a] Trimethoprim Viatris [MQ] |
| | | | [B]11.04 | *34.81 | 25.17 | [a] Alprim [AF] | |
| | | | [B]15.92 | *39.69 | 25.17 | [a] Triprim [RW] | |

*Combinations of sulfonamides and trimethoprim, incl. derivatives*

### ▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3103H NP | ‡1 | 1 | .. | 21.29 | 22.69 | Septrin [RW] |

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3391L DP | ‡1 | .. | .. | 21.29 | 22.69 | Septrin [RW] |

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2951H NP | 1 | 1 | .. | 15.68 | 17.08 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]4.17 | 19.85 | 17.08 | [a] Septrin Forte [RW] | |

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3390K DP | 1 | .. | .. | 15.68 | 17.08 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]4.17 | 19.85 | 17.08 | [a] Septrin Forte [RW] | |

### ▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**Authority required (STREAMLINED)**

***6201***

Prophylaxis of Pneumocystis jiroveci pneumonia

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10784N | 3 | 2 | .. | *21.06 | 22.46 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]12.51 | *33.57 | 22.46 | [a] Septrin Forte [RW] | |

## MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

### ▪ AZITHROMYCIN

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

**Restricted benefit**
Trachoma

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

8201P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #28.49 | 30.00 | Zithromax [PF] |

**azithromycin 500 mg tablet, 2**

8336R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 17.38 | 18.78 | [a] APO-Azithromycin [TX]<br>[a] Azithromycin Sandoz [SZ]<br>[a] Zithromax [PF] | [a] Azithromycin Mylan [AF]<br>[a] ZITHRO [RW] |

### ▪ AZITHROMYCIN

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

**Restricted benefit**
Urethritis
**Clinical criteria:**
- The condition must be uncomplicated and due to Chlamydia trachomatis.

**Restricted benefit**
Cervicitis
**Clinical criteria:**
- The condition must be uncomplicated and due to Chlamydia trachomatis.

**azithromycin 500 mg tablet, 2**

8200N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 17.38 | 18.78 | [a] APO-Azithromycin [TX]<br>[a] Azithromycin Sandoz [SZ]<br>[a] Zithromax [PF] | [a] Azithromycin Mylan [AF]<br>[a] ZITHRO [RW] |

### ▪ CLARITHROMYCIN

**clarithromycin 250 mg tablet, 14**

8318T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 16.65 | 18.05 | [a] Clarithro 250 [RW]<br>[a] Clarithromycin Sandoz [SZ]<br>[a] NOUMED CLARITHROMYCIN [VO] | [a] Clarithromycin AN [EA]<br>[a] Kalixocin [AF] |
| | | [B]3.33 | 19.98 | 18.05 | [a] Klacid [GO] | |

### ▪ CLARITHROMYCIN

**Restricted benefit**
Bordetella pertussis

**Restricted benefit**
Atypical mycobacterial infections

**clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL**

9192T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #32.16 | 30.00 | Klacid [GO] |

### ▪ ERYTHROMYCIN

**erythromycin 250 mg enteric capsule, 25**

1404X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 23.17 | 24.57 | [a] Eryc [YN] | [a] Mayne Pharma Erythromycin [YT] |

**erythromycin 250 mg enteric capsule, 25**

3325B DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 23.17 | 24.57 | [a] Eryc [YN] | [a] Mayne Pharma Erythromycin [YT] |

### ▪ ERYTHROMYCIN

**Authority required (STREAMLINED)**

***6160***
Severe acne
**Clinical criteria:**
- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

10780J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *33.35 | 30.00 | [a] Eryc [YN] | [a] Mayne Pharma Erythromycin [YT] |

## ▪ ERYTHROMYCIN ETHYLSUCCINATE

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

2424N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | #20.92 | 22.72 | E-Mycin 200 [AF] |

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

3334L (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #20.92 | 22.72 | E-Mycin 200 [AF] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

2428T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | #22.16 | 23.96 | E-Mycin 400 [AF] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

3337P (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | #22.16 | 23.96 | E-Mycin 400 [AF] |

## ▪ ROXITHROMYCIN

**roxithromycin 150 mg tablet, 10**

5260W (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.01 | 17.41 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 150 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

**roxithromycin 300 mg tablet, 5**

5261X (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.01 | 17.41 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 300 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

## ▪ ROXITHROMYCIN

**Authority required (STREAMLINED)**
***10404***
Infection
**Clinical criteria:**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**roxithromycin 150 mg tablet, 10**

12001P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *19.03 | 20.43 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 150 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

**roxithromycin 300 mg tablet, 5**

11993F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *19.03 | 20.43 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 300 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

## ▪ ROXITHROMYCIN

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

**roxithromycin 150 mg tablet, 10**

1760P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.01 | 17.41 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 150 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

**roxithromycin 300 mg tablet, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8016X NP | 1 | .. | .. | 16.01 | 17.41 | [a] APO-Roxithromycin [TX]<br>[a] Roxar 300 [RW]<br>[a] Roxithromycin Sandoz [SZ] | [a] APX-Roxithromycin [TY]<br>[a] Roximycin [AF] |

*Lincosamides*

## ▪ CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5057E DP | 1 | .. | .. | 18.53 | 19.93 | [a] APO-Clindamycin [TX]<br>[a] Clindamycin BNM [BZ]<br>[a] Clindamyk [AF] | [a] Calindamin [RW]<br>[a] Clindamycin LU [LV]<br>[a] Dalacin C [PF] |

## ▪ CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3138E NP MW | 2 | 1 | .. | *24.07 | 25.47 | [a] APO-Clindamycin [TX]<br>[a] Clindamycin BNM [BZ]<br>[a] Clindamyk [AF] | [a] Calindamin [RW]<br>[a] Clindamycin LU [LV]<br>[a] Dalacin C [PF] |

## ▪ LINCOMYCIN

**Note** Pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL vials and pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules are equivalent for the purposes of substitution.

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11366F DP | 1 | .. | .. | 77.27 | 30.00 | [a] LINCOMYCIN SXP [XN] |

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11380Y NP MW | 1 | .. | .. | 77.27 | 30.00 | [a] LINCOMYCIN SXP [XN] |

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2530E NP MW | 1 | .. | .. | 77.27 | 30.00 | [a] Lincocin [PF] |

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5144R DP | 1 | .. | .. | 77.27 | 30.00 | [a] Lincocin [PF] |

# AMINOGLYCOSIDE ANTIBACTERIALS

*Other aminoglycosides*

## ▪ GENTAMICIN

**gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2824P NP | 1 | 1 | .. | 24.51 | 25.91 | Pfizer Australia Pty Ltd [PF] |

## ▪ TOBRAMYCIN

**Restricted benefit**

Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

**tobramycin 500 mg/5 mL injection, 10 x 5 mL vials**

9480Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 193.35 | 30.00 | Tobra-Day [FF] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**
***5520***
Proven Pseudomonas aeruginosa infection
**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

5442K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 799.42 | 30.00 | [a] Tobi [GO]<br>[a] Tobramycin WKT [LI] | [a] TOBRAMYCIN SUN [RA] |

## ▪ TOBRAMYCIN

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
**Restricted benefit**
Septicaemia, suspected
**Restricted benefit**
Septicaemia, proven

**tobramycin 80 mg/2 mL injection, 5 x 2 mL vials**

1356J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 1 | .. | *39.43 | 30.00 | [a] DBL Tobramycin [PF]<br>[a] Tobramycin Viatris [AL] | [a] Tobramycin Mylan [AF] |

**tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5**

8872Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *41.95 | 30.00 | Pfizer Australia Pty Ltd [PF] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**
***4456***
Proven Pseudomonas aeruginosa infection
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

10066T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 2444.98 | 30.00 | TOBI podhaler [GO] |

## ▪ TOBRAMYCIN

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

**Authority required (STREAMLINED)**
***4513***
Proven Pseudomonas aeruginosa infection
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

10074F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2444.98 | 30.00 | TOBI podhaler [GO] |

## QUINOLONE ANTIBACTERIALS

*Fluoroquinolones*

### ▪ CIPROFLOXACIN

**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**ciprofloxacin 500 mg tablet, 14**

1209P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 18.21 | 19.61 | [a] APO-Ciprofloxacin [TX]<br>[a] C-Flox 500 [AL]<br>[a] Ciprofloxacin Sandoz [SZ]<br>[a] NOUMED CIPROFLOXACIN [VO] | [a] APX-Ciprofloxacin [TY]<br>[a] Cifran [RA]<br>[a] Ciprol 500 [RW] |

**ciprofloxacin 750 mg tablet, 14**

1210Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 20.79 | 22.19 | [a] APO-Ciprofloxacin [TX] | [a] APX-Ciprofloxacin [TY] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| NP | | | | | | [a] C-Flox 750 [AL]<br>[a] Ciprol 750 [RW] | [a] Ciprofloxacin Sandoz [SZ]<br>[a] NOUMED CIPROFLOXACIN [VO] |

## ▪ CIPROFLOXACIN

**Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Gonorrhoea

**ciprofloxacin 250 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1208N | | | | | | | |
| NP | 1 | .. | .. | 16.88 | 18.28 | [a] APO-Ciprofloxacin [TX]<br>[a] C-Flox 250 [AL]<br>[a] Ciprol 250 [RW] | [a] APX-Ciprofloxacin [TY]<br>[a] Ciprofloxacin Sandoz [SZ] |

## ▪ NORFLOXACIN

**Authority required**

Acute bacterial enterocolitis

**Authority required**

Complicated urinary tract infection

**norfloxacin 400 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3010K | | | | | | | |
| NP | 1 | 1 | .. | 16.90 | 18.30 | [a] APO-Norfloxacin [TX]<br>[a] Roxin [RW] | [a] Nufloxib [AF] |

## OTHER ANTIBACTERIALS

*Glycopeptide antibacterials*

## ▪ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 1 g injection, 1 vial**

2269K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 19.44 | 20.84 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

**vancomycin 500 mg injection, 1 vial**

3130R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *21.59 | 22.99 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

## ▪ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 1 g injection, 1 vial**

5083M DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 19.44 | 20.84 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

**vancomycin 500 mg injection, 1 vial**

3323X DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *21.59 | 22.99 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

## ▪ VANCOMYCIN

**Restricted benefit**

Endophthalmitis

**Restricted benefit**

Infection

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

**vancomycin 1 g injection, 1 vial**

2270L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *32.34 | 30.00 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

**vancomycin 500 mg injection, 1 vial**

3131T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5 | .. | .. | *34.47 | 30.00 | [a] Vancomycin Alphapharm [AF] | [a] Vancomycin Viatris [AL] |

*Steroid antibacterials*

## ▪ FUSIDATE

**Restricted benefit**

Serious staphylococcal infections

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

**sodium fusidate 250 mg tablet, 36**

2312Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 75.73 | 30.00 | Fucidin [LO] |

## ▪ FUSIDATE

**Authority required (STREAMLINED)**

***6133***

Osteomyelitis

**Clinical criteria:**

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

**sodium fusidate 250 mg tablet, 36**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10782L | 2 | 1 | .. | *139.75 | 30.00 | Fucidin [LO] |

*Imidazole derivatives*

## ▪ METRONIDAZOLE

**metronidazole 500 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1642K NP | ‡1 | .. | .. | 27.55 | 28.95 | Flagyl [SW] |

**metronidazole 500 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5157K DP | ‡1 | .. | .. | 27.55 | 28.95 | Flagyl [SW] |

**metronidazole 200 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1636D NP | 1 | 1 | .. | 15.90 | 17.30 | Metrogyl 200 [AF] |

**metronidazole 200 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3339R DP | 1 | .. | .. | 15.90 | 17.30 | Metrogyl 200 [AF] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1630T NP | ‡1 | .. | .. | 23.77 | 25.17 | Flagyl S [SW] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3341W DP | ‡1 | .. | .. | 23.77 | 25.17 | Flagyl S [SW] |

## ▪ METRONIDAZOLE

**Restricted benefit**
Anaerobic infections

**metronidazole 400 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1621H NP | 1 | 1 | .. | 16.67 | 18.07 | [a] Metrogyl 400 [AF] |
| | | | [B]1.86 | 18.53 | 18.07 | [a] Flagyl [SW] |

## ▪ METRONIDAZOLE

**Restricted benefit**
Anaerobic infections

**metronidazole 400 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5155H DP | 1 | .. | .. | 16.67 | 18.07 | [a] Metrogyl 400 [AF] |
| | | | [B]1.86 | 18.53 | 18.07 | [a] Flagyl [SW] |

*Nitrofuran derivatives*

## ▪ NITROFURANTOIN

**Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

**nitrofurantoin 100 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1693D NP MW | 1 | 1 | .. | 26.98 | 28.38 | [a] APO-Nitrofurantoin [TX]<br>[a] Nitrofurantoin BNM [BZ] | [a] ARX-Nitrofurantoin [XT] |

**nitrofurantoin 50 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1692C NP MW | 1 | 1 | .. | 22.96 | 24.36 | [a] APO-Nitrofurantoin [TX]<br>[a] Nitrofurantoin BNM [BZ] | [a] ARX-Nitrofurantoin [XT] |

*Other antibacterials*

## ▪ METHENAMINE HIPPURATE

**methenamine hippurate 1 g tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3124K NP | 1 | 5 | .. | 31.29 | 30.00 | [a] Hiprex [IL] | [a] Uramet [AS] |

# ANTIMYCOTICS FOR SYSTEMIC USE

## ANTIMYCOTICS FOR SYSTEMIC USE

*Triazole and tetrazole derivatives*

### FLUCONAZOLE

**Note** Not for use in vulvovaginal candida infections.

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

**Authority required (STREAMLINED)**

***6002***

Cryptococcal meningitis

**Authority required (STREAMLINED)**

***5978***

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

***6023***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

***5989***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

***6030***

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

***7898***

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 100 mg capsule, 28**

1472L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.62 | 30.00 | [a] Diflucan [PF] | [a] Dizole 100 [AF] |
| | | | | | [a] Fluconazole Sandoz [SZ] | [a] Ozole [RA] |

**fluconazole 200 mg capsule, 28**

1475P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.40 | 30.00 | [a] Diflucan [PF] | [a] Dizole 200 [AF] |
| | | | | | [a] Fluconazole APOTEX [GX] | [a] Fluconazole Sandoz [SZ] |
| | | | | | [a] Fluzole 200 [RW] | [a] Ozole [RA] |

**fluconazole 50 mg capsule, 28**

1471K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.54 | 22.94 | [a] Dizole 50 [AF] | [a] Fluconazole Sandoz [SZ] |
| | | | | | [a] Ozole [RA] | |
| | | [B]4.81 | 26.35 | 22.94 | [a] Diflucan [PF] | |

### FLUCONAZOLE

**Note** Not for use in vulvovaginal candida infections.

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

**Authority required (STREAMLINED)**

***6006***

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

***6045***

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

***6031***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

***6046***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

***6032***

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

***7934***

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**fluconazole 50 mg/5 mL powder for oral liquid, 35 mL**

5446P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | #69.59 | 30.00 | Diflucan [PF] |

## ▪ ITRACONAZOLE

**Note** Not for use in vulvovaginal candida infections.

**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules. The recommended dose for Lozanoc is therefore half the recommended dose for conventional itraconazole capsules. Lozanoc 50 mg capsules and conventional itraconazole 100 mg capsules are not interchangeable.

**Note** Not for use in superficial mycoses

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

**Authority required (STREAMLINED)**

***6022***

Systemic aspergillosis

**Authority required (STREAMLINED)**

***6005***

Systemic sporotrichosis

**Authority required (STREAMLINED)**

***6057***

Systemic histoplasmosis

**Authority required (STREAMLINED)**

***5988***

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Authority required (STREAMLINED)**

***6037***

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Authority required (STREAMLINED)**

***6016***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

***6035***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**itraconazole 50 mg capsule, 60**

10732W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 117.75 | 30.00 | Lozanoc [YN] |

**itraconazole 100 mg capsule, 60**

8196J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 117.75 | 30.00 | [a] APO-Itraconazole [TX]<br>[a] ITRANOX [RW] | [a] Itracap [AF] |

## ▪ POSACONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note Shared Care Model**:

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

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**posaconazole 100 mg modified release tablet, 24**

10460M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 203.79 | 30.00 | [a] Pharmacor Posaconazole [CR]<br>[a] POSACONAZOLE DR.REDDY'S [RZ]<br>[a] Posaconazole Sandoz [SZ] | [a] Posaconazole ARX [XT]<br>[a] Posaconazole Juno [JU] |

## ▪ VORICONAZOLE

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

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

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

10168E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | #506.82 | 30.00 | Vfend [PF] |

**voriconazole 200 mg tablet, 56**

10198R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 615.22 | 30.00 | [a] Vfend [PF]<br>[a] Vttack [AF] | [a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] |

**voriconazole 50 mg tablet, 56**

10173K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 159.80 | 30.00 | [a] Vfend [PF]<br>[a] Vttack [AF] | [a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] |

## ▪ VORICONAZOLE

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

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

**Authority required**

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 200 mg tablet, 56**

9364W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 615.22 | 30.00 | [a] Vfend [PF] | [a] Voriconazole Sandoz [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Vttack [AF] | [a] Vzole [RW] |

NP **voriconazole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9363T | 1 | 2 | .. | 159.80 | 30.00 | [a] Vfend [PF]<br>[a] Vttack [AF] | [a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] |

NP

## ▪ VORICONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by Scedosporium species; OR
- The condition must caused by Fusarium species.

**Authority required**

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9452L | 1 | .. | .. | #506.82 | 30.00 | Vfend [PF] |

NP

# ▪ ANTIMYCOBACTERIALS

## DRUGS FOR TREATMENT OF TUBERCULOSIS

*Antibiotics*

## ▪ RIFAMPICIN

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

**Authority required**

Mycobacterium ulcerans infection (Buruli ulcer)

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer.

**rifampicin 300 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12189M | 12 | .. | .. | *110.37 | 30.00 | Rimycin 300 [AF] |

NP

**rifampicin 300 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12215X | 1 | .. | .. | 94.06 | 30.00 | Rimycin 300 [AF] |

NP

**rifampicin 150 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12200D | 12 | .. | .. | *232.05 | 30.00 | Rimycin 150 [AF] |

NP

**rifampicin 150 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12190N NP | 1 | .. | .. | 194.72 | 30.00 | Rimycin 150 [AF] |

*Hydrazides*

## ▪ ISONIAZID

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

**isoniazid 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1554T NP | 1 | 2 | .. | 21.26 | 22.66 | Arrow Pharma Pty Ltd [RW] |

## DRUGS FOR TREATMENT OF LEPRA

*Drugs for treatment of lepra*

## ▪ DAPSONE

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

**dapsone 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1272Y NP | 1 | 1 | .. | 400.67 | 30.00 | Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8801F NP | 1 | 1 | .. | 327.98 | 30.00 | Link Medical Products Pty Ltd [LM] |

## ▪ RIFAMPICIN

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

**Authority required**
Leprosy
**Population criteria:**
- Patient must be an adult.

**rifampicin 300 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1983J NP | 1 | .. | .. | 94.06 | 30.00 | Rimycin 300 [AF] |

**rifampicin 150 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1982H NP | 1 | .. | .. | 194.72 | 30.00 | Rimycin 150 [AF] |

## ▪ RIFAMPICIN

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

**Restricted benefit**
Meningococcal disease
**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

**Restricted benefit**
Haemophilus influenzae type B
**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

**rifampicin 300 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1984K NP | 1 | .. | .. | 21.10 | 22.50 | Rimycin 300 [AF] |

**rifampicin 100 mg/5 mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8025J NP | ‡1 | .. | .. | 26.13 | 27.53 | Rifadin [SW] |

**rifampicin 150 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1981G NP | 1 | .. | .. | 30.77 | 30.00 | Rimycin 150 [AF] |

# ANTIVIRALS FOR SYSTEMIC USE

## DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5942***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1007B NP | 1 | 5 | .. | 34.43 | 30.00 | [a] Aciclovir APOTEX [TY]<br>[a] Aciclovir Sandoz [HX]<br>[a] GenRx Aciclovir [GX] | [a] Aciclovir GH [GQ]<br>[a] APO-Aciclovir [TX] |

### ACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

***5967***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**

***5959***

Herpes zoster ophthalmicus

**aciclovir 800 mg tablet, 35**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1052J NP | 1 | .. | .. | 38.92 | 30.00 | [a] Aciclovir APOTEX [TY]<br>[a] APO-Aciclovir [TX] | [a] Aciclovir Sandoz [HX] |

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***5936***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1003T NP | 2 | .. | .. | *24.91 | 26.31 | [a] Aciclovir Sandoz [HX] |

**aciclovir 200 mg tablet, 50**

1555W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 24.90 | 26.30 | [a] Aciclovir APOTEX [TY] | [a] APO-Aciclovir [TX] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5937***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 20**

2274Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 31.64 | 30.00 | [a] APO-Famciclovir [TX] | [a] Famciclovir-GA [ED] |
| | | | | | [a] Famvir [IX] | [a] Favic 250 [RW] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5937***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 125 mg tablet, 40**

8092X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 31.64 | 30.00 | [a] APO-Famciclovir [TX] | [a] Famciclovir-GA [ED] |
| | | | | | [a] Famvir [IX] | [a] Favic 125 [RW] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5971***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 56**

8217L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 65.22 | 30.00 | [a] APO-Famciclovir [TX] | [a] Ezovir [AF] |
| | | | | | [a] Famvir [IX] | [a] Favic 250 [RW] |

## ▪ FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

***5951***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 250 mg tablet, 21**

8002E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 32.58 | 30.00 | [a] APO-Famciclovir [TX] | [a] Ezovir [AF] |
| | | | | | [a] Famciclovir-GA [ED] | [a] Famvir [IX] |
| | | | | | [a] Favic 250 [RW] | |

## ▪ FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

***5943***

Herpes zoster

**Clinical criteria:**

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 500 mg tablet, 30**

8897G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 40.99 | 30.00 | [a] APO-Famciclovir [TX]<br>[a] Favic 500 [RW] | [a] Famvir [IX] |

## ▪ FAMCICLOVIR

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority required (STREAMLINED)**

***5954***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

**Clinical criteria:**

- Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

***5947***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

***5948***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

***5949***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 500 mg tablet, 56**

8896F

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 65.26 | 30.00 | [a] APO-Famciclovir [TX]<br>[a] Famciclovir-GA [ED]<br>[a] Favic 500 [RW] | [a] Ezovir [AF]<br>[a] Famvir [IX] |

## ▪ MOLNUPIRAVIR

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

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

**Note** This drug should be considered for use only if nirmatrelvir (&) ritonavir is contraindicated or otherwise unsuitable.

**Authority required (STREAMLINED)**

***13759***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**

- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

***13824***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

***13748***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/$m^2$)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

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**Authority required (STREAMLINED)**

***13765***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/$m^2$),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

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**molnupiravir 200 mg capsule, 40**

12910L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1102.24 | 30.00 | Lagevrio [MK] |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5940***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

5480K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.89 | 27.29 | [a] APX-Valaciclovir [TY] | [a] NOUMED VALACICLOVIR [VO] |
| | | | | | [a] Shilova 500 [ZS] | [a] Vaclovir [AF] |
| | | | | | [a] Valaciclovir APOTEX [GX] | [a] Valaciclovir generichealth [GQ] |
| | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | [a] Valaciclovir SZ [HX] | [a] Valacor 500 [CR] |
| | | | | | [a] Zelitrex [RF] | |
| | | [B]2.43 | 28.32 | 27.29 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

***5961***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

8134D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.89 | 27.29 | [a] APX-Valaciclovir [TY] | [a] NOUMED VALACICLOVIR [VO] |
| | | | | | [a] Shilova 500 [ZS] | [a] Vaclovir [AF] |
| | | | | | [a] Valaciclovir APOTEX [GX] | [a] Valaciclovir generichealth [GQ] |
| | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | [a] Valaciclovir SZ [HX] | [a] Valacor 500 [CR] |
| | | | | | [a] Zelitrex [RF] | |
| | | [B]2.43 | 28.32 | 27.29 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

**Authority required (STREAMLINED)**

***5960***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 10**

8133C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *21.59 | 22.99 | [a] APX-Valaciclovir [TY] | [a] Vaclovir [AF] |
| | | | | | [a] Valaciclovir APOTEX [GX] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | [a] Zelitrex [RF] | |
| | | [B]5.40 | *26.99 | 22.99 | [a] Valtrex [RW] | |

## ▪ VALACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

***5962***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)**

***5968***

Herpes zoster ophthalmicus

**valaciclovir 500 mg tablet, 42**

8064K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 31.05 | 30.00 | [a] APX-Valaciclovir [TY] | [a] Vaclovir [AF] |
| | | | | | [a] Valaciclovir APOTEX [GX] | [a] Valaciclovir generichealth [GQ] |
| | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | [a] Valacor 500 [CR] | [a] Zelitrex [RF] |
| | | [B]2.43 | 33.48 | 30.00 | [a] Valtrex [RW] | |

*Protease inhibitors*

## ▪ NIRMATRELVIR (&) RITONAVIR

**Caution** Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

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

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

**Authority required (STREAMLINED)**

***13759***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

***13821***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

***13748***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

2. The patient has disability with multiple comorbidities and/or frailty

3. Neurological conditions, including stroke and dementia and demyelinating conditions

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/$m^2$)

7. Diabetes type I or II, requiring medication for glycaemic control

8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

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**Authority required (STREAMLINED)**

***14187***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at high risk of requiring hospitalisation for COVID-19 infection, **AND**
- Patient must be at least 50 years old, but not older than 60 years; OR
- Patient must be at least 60 years old, but not older than 70 years.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/$m^2$)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

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

12996B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 1114.84 | 30.00 | Paxlovid [HD] |

*Antivirals for treatment of HCV infections*

## ▪ GLECAPREVIR + PIBRENTASVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11344C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 17895.47 | 30.00 | Maviret [VE] |

## ▪ GLECAPREVIR + PIBRENTASVIR

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11353M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 17895.47 | 30.00 | Maviret [VE] |

## ▪ GLECAPREVIR + PIBRENTASVIR

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11354N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 17895.47 | 30.00 | Maviret [VE] |

## ▪ RIBAVIRIN

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 200 mg tablet, 100**

12785X (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *1062.33 | 30.00 | Ibavyr [IX] |

## ▪ SOFOSBUVIR + VELPATASVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

11147Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 12037.13 | 30.00 | Epclusa [GI] |

## ▪ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28**

11658N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 12037.13 | 30.00 | Vosevi [GI] |

*Antivirals for treatment of HIV infections, combinations*

## ▪ TENOFOVIR DISOPROXIL + EMTRICITABINE

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

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

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

**tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30**

12542D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 38.15 | 30.00 | [a] Tenofovir/Emtricitabine Sandoz 301/200 [SZ] |

**tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30**

11306C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 38.15 | 30.00 | [a] Tenofovir EMT GH [GQ] |

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

11296M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 38.15 | 30.00 | [a] Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF] | [a] Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL] |

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

11276L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 38.15 | 30.00 | [a] CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR] | [a] Tenofovir/Emtricitabine 300/200 APOTEX [TX] |

# ▪ VACCINES

## BACTERIAL VACCINES

*Tetanus vaccines*

## ▪ DIPHTHERIA + TETANUS VACCINE

**Note** For immunisation of adults and children aged greater than or equal to 8 years.

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

8783G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 71.43 | 30.00 | ADT Booster [CS] |

# ▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

# ▪ ANTINEOPLASTIC AGENTS

## ALKYLATING AGENTS

*Nitrogen mustard analogues*

## ▪ CHLORAMBUCIL

**chlorambucil 2 mg tablet, 25**

1163F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 2 | .. | *136.25 | 30.00 | Leukeran [AS] |

## ▪ CYCLOPHOSPHAMIDE

**cyclophosphamide 50 mg tablet, 50**

1266P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 156.62 | 30.00 | Cyclonex [GH] |

## ▪ MELPHALAN

**melphalan 2 mg tablet, 25**

2547C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 64.94 | 30.00 | Alkeran [AS] |

*Alkyl sulfonates*

## ▪ BUSULFAN

**busulfan 2 mg tablet, 100**

1128J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 79.02 | 30.00 | Myleran [AS] |

*Nitrosoureas*

## ▪ CARMUSTINE

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

**Restricted benefit**

Glioblastoma multiforme

**Clinical criteria:**

- The condition must be suspected or confirmed at the time of initial surgery.

**carmustine 7.7 mg implant, 8**

8898H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 11150.45 | 30.00 | Gliadel [EI] |

*Other alkylating agents*

## ▪ TEMOZOLOMIDE

**temozolomide 180 mg capsule, 5**

2438H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 161.90 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temodal [MK] |

**temozolomide 20 mg capsule, 5**

8379B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 33.47 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temizole 20 [AL] |

**temozolomide 250 mg capsule, 5**

8381D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 226.96 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK] | [a] Temizole 250 [AL]<br>[a] Temozolomide Juno [JX] |

**temozolomide 100 mg capsule, 5**

8380C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 100.76 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK] | [a] Temizole 100 [AL]<br>[a] Temozolomide Juno [JX] |

**temozolomide 140 mg capsule, 5**

9362R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 135.09 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK] | [a] Temizole 140 [AL]<br>[a] Temozolomide Juno [JX] |

**temozolomide 5 mg capsule, 5**

8378Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.96 | 21.36 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temizole 5 [AL] |

## ▪ TEMOZOLOMIDE

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

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

**Restricted benefit**

Glioblastoma multiforme

**Treatment criteria:**

- Patient must be undergoing concomitant radiotherapy.

**temozolomide 180 mg capsule, 5**

10062N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *469.71 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temodal [MK] |

**temozolomide 20 mg capsule, 5**

8820F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *74.43 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temizole 20 [AL] |

**temozolomide 100 mg capsule, 5**

8821G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *284.46 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK] | [a] Temizole 100 [AL]<br>[a] Temozolomide Juno [JX] |

**temozolomide 140 mg capsule, 5**

9361Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *389.31 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temodal [MK] | [a] Temizole 140 [AL]<br>[a] Temozolomide Juno [JX] |

**temozolomide 5 mg capsule, 5**

8819E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 2 | .. | *33.90 | 30.00 | [a] APO-Temozolomide [TX]<br>[a] Temozolomide Juno [JX] | [a] Temizole 5 [AL] |

## ANTIMETABOLITES

*Folic acid analogues*

### ▪ METHOTREXATE

**methotrexate 5 mg/2 mL injection, 5 x 2 mL vials**

2396D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 41.84 | 30.00 | DBL Methotrexate [PF] |

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

2395C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 40.41 | 30.00 | DBL Methotrexate [PF] |

**methotrexate 10 mg tablet, 15**

2272N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 25.09 | 26.49 | Methoblastin [PF] |

**methotrexate 2.5 mg tablet, 30**

1622J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 18.82 | 20.22 | Methoblastin [PF] |

### ▪ METHOTREXATE

**Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

1623K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 53.31 | 30.00 | Methoblastin [PF] |

*Purine analogues*

### ▪ FLUDARABINE

**fludarabine phosphate 10 mg tablet, 20**

9184J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 938.37 | 30.00 | Fludara [GZ] |

### ▪ MERCAPTOPURINE

**mercaptopurine monohydrate 20 mg/mL oral liquid, 100 mL**

10214N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 381.21 | 30.00 | Allmercap [LM] |

**mercaptopurine monohydrate 50 mg tablet, 25**

1598D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 2 | .. | *168.77 | 30.00 | [a] MERCAPTOPURINE-LINK [LM] |
| | | [B]7.44 | *176.21 | 30.00 | [a] Purinethol [AS] |

### ▪ TIOGUANINE

**tioguanine 40 mg tablet, 25**

1233X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 194.29 | 30.00 | Lanvis [AS] |

*Pyrimidine analogues*

## ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

**azacitidine 200 mg tablet, 7**

13623B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *13389.89 | 30.00 | Onureg [CJ] |

## ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Dose escalation therapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail:

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.

All reports must be documented in the patient's medical records.

**azacitidine 300 mg tablet, 7**

13624C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 1 | .. | *20003.79 | 30.00 | Onureg [CJ] |

## ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

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

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Initial treatment

**Clinical criteria:**

- Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy, **AND**
- Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation, **AND**
- Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk, **AND**
- Patient must not have undergone a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than 1.0 x $10^9$/L and platelet count greater than or equal to 100 x $10^9$/L.

A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than 1.0 x $10^9$/L or platelet count less than 100 x $10^9$/L.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

**azacitidine 300 mg tablet, 7**

13619T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *13371.85 | 30.00 | Onureg [CJ] |

## ▪ CAPECITABINE

**capecitabine 150 mg tablet, 60**

8361C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 21.53 | 22.93 | Capecitabine-DRLA [RZ] |

**capecitabine 500 mg tablet, 120**

8362D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 65.93 | 30.00 | [a] Capecitabine Alphapharm [AF] | [a] Capecitabine-DRLA [RZ] |
| | | | | | [a] Capecitabine Sandoz [SZ] | [a] Xelabine [AL] |

## ▪ DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***13258***

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13081L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4862.13 | 30.00 | Inqovi 35/100 [OS] |

## ▪ DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
PBS Authorities
GPO Box 9826
[Your capital city]

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) full blood examination report

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13133F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4862.13 | 30.00 | Inqovi 35/100 [OS] |

## ▪ DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

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

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

(b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

(c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

(e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

(a) The patient's International Prognostic Scoring System (IPSS) score.

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

(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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

(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and

(b) full blood examination report.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13087T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4862.13 | 30.00 | Inqovi 35/100 [OS] |

## ▪ DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

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

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13107W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4862.13 | 30.00 | Inqovi 35/100 [OS] |

## ▪ TRIFLURIDINE + TIPIRACIL

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10309***

Metastatic colorectal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; OR
- Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

**Authority required (STREAMLINED)**

***8183***

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

11507P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 2 | .. | *2283.57 | 30.00 | Lonsurf 15/6.14 [SE] |

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

11524M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 2 | .. | *3933.61 | 30.00 | Lonsurf 20/8.19 [SE] |

## ▪ TRIFLURIDINE + TIPIRACIL

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10252***

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

**Authority required (STREAMLINED)**

***10310***

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

12056M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 2 | .. | *2283.57 | 30.00 | Lonsurf 15/6.14 [SE] |

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

12033H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 2 | .. | *3933.61 | 30.00 | Lonsurf 20/8.19 [SE] |

## PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

*Vinca alkaloids and analogues*

### ▪ VINORELBINE

**Authority required**

Advanced breast cancer

**Clinical criteria:**

- Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

**vinorelbine 20 mg capsule, 1**

9009E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 20 | 2 | .. | *1579.37 | 30.00 | [a] Navelbine [FB] | [a] Velabine [LI] |

**vinorelbine 30 mg capsule, 1**

9010F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 16 | 2 | .. | *1892.69 | 30.00 | [a] Navelbine [FB] | [a] Velabine [LI] |

*Podophyllotoxin derivatives*

### ▪ ETOPOSIDE

**etoposide 100 mg capsule, 10**

1389D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 392.62 | 30.00 | Vepesid [LM] |

**etoposide 50 mg capsule, 20**

1396L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 449.54 | 30.00 | Vepesid [LM] |

## PROTEIN KINASE INHIBITORS

*BCR-ABL tyrosine kinase inhibitors*

### ▪ ASCIMINIB

**Note** Special Pricing Arrangements apply.

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

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

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

**Authority required (STREAMLINED)**

***13923***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**asciminib 40 mg tablet, 60**

13259W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6131.32 | 30.00 | Scemblix [NV] |

### ▪ ASCIMINIB

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

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

**Note** Special Pricing Arrangements apply.

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

**Authority required (STREAMLINED)**

***13923***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**asciminib 20 mg tablet, 60**

13268H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6174.63 | 30.00 | Scemblix [NV] |

## ▪ ASCIMINIB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib

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

**Note** Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients without T315I mutation

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be in the blast phase, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors; OR
- Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors; OR
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or

(iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

**asciminib 20 mg tablet, 60**

13248G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6174.63 | 30.00 | Scemblix [NV] |

**asciminib 40 mg tablet, 60**

13264D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6131.32 | 30.00 | Scemblix [NV] |

## ▪ ASCIMINIB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients with T315I mutation

**Clinical criteria:**

- The condition must not be in the blast phase, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or

(iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib, (iv) ponatinib

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing Treatment for patients with T315I mutation

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or

(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

**asciminib 40 mg tablet, 60**

13260X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 5 | .. | *30224.62 | 30.00 | Scemblix [NV] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood

BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

**Authority required (STREAMLINED)**

***12522***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

12842X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

12888H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

12857Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

12866E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

**Authority required (STREAMLINED)**

***12565***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

12889J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

12869H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

12843Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

12890K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting. Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for third-line treatment of CML.
1. Initial third-line treatment
Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.
2. Continuing treatment for third-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR

- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of nilotinib is defined as:

(i) Lack of response to second line nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with nilotinib; OR

ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

12902C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT]<br>[a] Dasatinib SUN [RA]<br>[a] Sprycel [BQ] | [a] Dasatinib Dr.Reddy's [RI]<br>[a] DASATINIB-TEVA [TB]<br>[a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

12849G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT]<br>[a] Dasatinib SUN [RA]<br>[a] Sprycel [BQ] | [a] Dasatinib Dr.Reddy's [RI]<br>[a] DASATINIB-TEVA [TB]<br>[a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

12865D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT]<br>[a] Dasatinib SUN [RA]<br>[a] Sprycel [BQ] | [a] Dasatinib Dr.Reddy's [RI]<br>[a] DASATINIB-TEVA [TB]<br>[a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

12886F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT]<br>[a] Dasatinib SUN [RA]<br>[a] Sprycel [BQ] | [a] Dasatinib Dr.Reddy's [RI]<br>[a] DASATINIB-TEVA [TB]<br>[a] TE-DASATINIB [AF] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for second-line treatment of CML.
1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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**Authority required (STREAMLINED)**

***12530***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

12859T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

12850H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

12860W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

12903D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

| 1416M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

| 1354G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

| 1381Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

| 1415L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for second-line treatment of CML.
1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**dasatinib 100 mg tablet, 30**

9342Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

2478K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

2482P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

2485T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ DASATINIB

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

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib, **AND**
- The condition must not have progressed.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**dasatinib 100 mg tablet, 30**

| 9343R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 20 mg tablet, 60**

| 9125G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1794.02 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 50 mg tablet, 60**

| 9126H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2874.63 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

**dasatinib 70 mg tablet, 60**

| 9127J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 3520.38 | 30.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib SUN [RA] | [a] DASATINIB-TEVA [TB] |
| | | | | | | [a] Sprycel [BQ] | [a] TE-DASATINIB [AF] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9176Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10918P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9179D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10921T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9175X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10925B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9173T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR] | [a] Glivec [AF] |
| | | | | | [a] IMATINIB RBX [RA] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10933K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR] | [a] Imatinib-APOTEX [TX] |
| | | | | | [a] IMATINIB-DRLA [RZ] | [a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9177B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR] | [a] Glivec [AF] |
| | | | | | [a] IMATINIB RBX [RA] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10939R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR] | [a] Imatinib-APOTEX [TX] |
| | | | | | [a] IMATINIB-DRLA [RZ] | [a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9178C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR] | [a] Glivec [AF] |
| | | | | | [a] IMATINIB RBX [RA] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10940T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9174W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10941W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9172R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10942X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9209***

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

11753N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11776T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9243***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

11765F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11756R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9243***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

11769K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11757T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9296***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

11758W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11763D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9206***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

11762C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11777W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9209***

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

11786H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11764E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9296***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

11781C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11770L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

***9206***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

11785G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11779Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***9278***

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**imatinib 100 mg tablet, 60**

11784F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

12710Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Imatinib-APOTEX [TX] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***9278***

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**imatinib 400 mg tablet, 30**

11788K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

12711B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

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

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 400 mg tablet, 30**

5444M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

12681K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

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

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 100 mg tablet, 60**

5443L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

12759M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Imatinib-APOTEX [TX] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

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

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

**Authority required (STREAMLINED)**

***13132***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 600 mg tablet, 30**

12919Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

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

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***9209***

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12923E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12927J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the

number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9113P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10915L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9114Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10916M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**

***12536***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**

- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

11752M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11772N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously

demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**

***12536***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

11775R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11782D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***13132***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 400 mg tablet, 30**

11778X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

12723P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***13132***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 100 mg tablet, 60**

11787J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

12722N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Imatinib-APOTEX [TX] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9111M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

12709X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Imatinib-APOTEX [TX] | [a] IMATINIB-DRLA [RZ] |

## ▪ IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9112N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR] | [a] Glivec [AF] |
| | | | | | [a] IMATINIB RBX [RA] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

12754G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Imatinib-APOTEX [TX] | [a] IMATINIB-DRLA [RZ] |
| | | | | | [a] Imatinib GH [GQ] | |

## ▪ IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The condition must have not achieved a response with this drug at a dose of 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12926H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9124F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10917N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9115R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10920R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

9123E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

10924Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report

documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

9116T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

10935M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***9207***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**imatinib 400 mg tablet, 30**

11789L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11771M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***9207***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**imatinib 100 mg tablet, 60**

11780B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11783E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***12542***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**Authority required (STREAMLINED)**

***12525***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**imatinib 400 mg tablet, 30**

11878E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

11870R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 481.29 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX]<br>[a] Imatinib GH [GQ] |

## ▪ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***12542***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**Authority required (STREAMLINED)**

***12525***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**imatinib 100 mg tablet, 60**

11880G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] Gilmat [CR]<br>[a] IMATINIB RBX [RA] | [a] Glivec [AF]<br>[a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

11875B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 244.64 | 30.00 | [a] CIPLA IMATINIB ADULT [LR]<br>[a] IMATINIB-DRLA [RZ] | [a] Imatinib-APOTEX [TX] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12911M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**

***12536***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12912N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

***9207***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**

- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**imatinib 600 mg tablet, 30**

12920B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12924F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***12542***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**Authority required (STREAMLINED)**

***12525***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**imatinib 600 mg tablet, 30**

12928K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR

indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12935T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 979.37 | 30.00 | Imatab [JU] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for second-line treatment of CML.

1. Initial second-line treatment
A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment for second-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***12563***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12858R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5057.67 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for third-line treatment of CML.
1. Initial third-line treatment
Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.
2. Continuing treatment for third-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***12522***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12867F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5057.67 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.
2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***12572***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**nilotinib 150 mg capsule, 120**

12868G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3857.02 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial First-line treatment
A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment
Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.
For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
3. Authority approval requirements
Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***12549***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12885E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5057.67 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.
Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.
Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.
Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.
Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.
Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.
Imatinib is not approved for third-line treatment of CML.

1. Initial third-line treatment
Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.
2. Continuing treatment for third-line treatment
For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
All pathology reports must be documented in the patient's medical records.
3. Authority approval requirements
Response criteria to initial treatment with dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
4. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
5. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of dasatinib is defined as:

(i) Lack of response to second-line dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed dasatinib for the chronic phase of chronic myeloid leukaemia.Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12887G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5057.67 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**nilotinib 150 mg capsule, 120**

1309X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3857.02 | 30.00 | Tasigna [NV] |

## ▪ NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

1. Initial second-line treatment

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment for second-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale,

must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to.

50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9171Q | 1 | 5 | .. | 5057.67 | 30.00 | Tasigna [NV] |

## ▪ PONATINIB

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or

3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and

3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or

4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ponatinib 15 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11454W | 1 | 2 | .. | 5490.31 | 30.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11453T | 1 | 2 | .. | 6173.78 | 30.00 | Iclusig [TK] |

## ▪ PONATINIB

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;

3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**ponatinib 15 mg tablet, 60**

10523W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 5490.31 | 30.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

10524X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6173.78 | 30.00 | Iclusig [TK] |

## ▪ PONATINIB

**Note** 1. Continuing treatment.
For first continuing applications patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment.
2. Authority approval requirements.
Response criteria to treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted within 18 months of the commencement of treatment with ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive first continuing treatment with this drug).

Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive subsequent continuing treatments with this drug.

3. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006).

4. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals.

The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or

(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.

A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ponatinib 15 mg tablet, 60**

10520Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5490.31 | 30.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

10530F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6173.78 | 30.00 | Iclusig [TK] |

*Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors*

## ▪ AFATINIB

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**afatinib 20 mg tablet, 28**

11335N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 30 mg tablet, 28**

11341X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 40 mg tablet, 28**

11359W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 50 mg tablet, 28**

11329G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

## ▪ AFATINIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7613***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**afatinib 20 mg tablet, 28**

11336P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 30 mg tablet, 28**

11348G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 40 mg tablet, 28**

11347F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

**afatinib 50 mg tablet, 28**

11342Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2886.13 | 30.00 | Giotrif [BY] |

## ▪ ERLOTINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 100 mg tablet, 30**

10020J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 608.00 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 150 mg tablet, 30**

10014C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 750.27 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 25 mg tablet, 30**

10022L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 173.30 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

## ▪ ERLOTINIB

**Authority required (STREAMLINED)**

***4600***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

**erlotinib 100 mg tablet, 30**

10019H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 608.00 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 150 mg tablet, 30**

10025P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 750.27 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 25 mg tablet, 30**

10028T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 173.30 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

## ▪ ERLOTINIB

**Authority required (STREAMLINED)**

***7446***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 100 mg tablet, 30**

11260P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 608.00 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 150 mg tablet, 30**

11259N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 750.27 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 25 mg tablet, 30**

11263T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 173.30 | 30.00 | [a] Erlotinib APOTEX [TX] | [a] Erlotinib Sandoz [SZ] |

## ▪ GEFITINIB

**Authority required (STREAMLINED)**

***7447***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**gefitinib 250 mg tablet, 30**

11264W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 536.37 | 30.00 | Cipla Gefitinib [LR] |

## ▪ GEFITINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**gefitinib 250 mg tablet, 30**

8769M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 536.37 | 30.00 | Cipla Gefitinib [LR] |

## ▪ OSIMERTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

**osimertinib 40 mg tablet, 30**

11620N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7972.13 | 30.00 | Tagrisso [AP] |

## ▪ OSIMERTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

**osimertinib 40 mg tablet, 30**

12233W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7972.13 | 30.00 | Tagrisso [AP] |

## ▪ OSIMERTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- Patient must not have previously received this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

**osimertinib 80 mg tablet, 30**

11622Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7972.13 | 30.00 | Tagrisso [AP] |

## ▪ OSIMERTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

**Population criteria:**

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

**osimertinib 80 mg tablet, 30**

12232T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7972.13 | 30.00 | Tagrisso [AP] |

*B-Raf serine-threonine kinase (BRAF) inhibitors*

## ▪ DABRAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11823G | 1 | 3 | .. | 7525.53 | 30.00 | Tafinlar [NV] |

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11820D | 1 | 3 | .. | 5071.07 | 30.00 | Tafinlar [NV] |

## ▪ DABRAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***10157***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2846T | 1 | 3 | .. | 7525.53 | 30.00 | Tafinlar [NV] |

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2963Y | 1 | 3 | .. | 5071.07 | 30.00 | Tafinlar [NV] |

## ▪ DABRAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6013***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10003L | 1 | 5 | .. | 7525.53 | 30.00 | Tafinlar [NV] |

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2954L | 1 | 5 | .. | 5071.07 | 30.00 | Tafinlar [NV] |

## ▪ ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12487***

Metastatic colorectal cancer
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have BRAF V600 variant positive metastatic colorectal cancer, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have received prior treatment with cetuximab for this condition; OR
- Patient must not have developed disease progression while receiving cetuximab for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have failed to respond to at least one other line of systemic therapy, **AND**
- Patient must have a WHO performance status of 2 or less.

**encorafenib 75 mg capsule, 42**

12814K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *5303.01 | 30.00 | Braftovi [FB] |

## ▪ ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***12484***
Metastatic colorectal cancer
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**encorafenib 75 mg capsule, 42**

12815L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *5303.01 | 30.00 | Braftovi [FB] |

## ▪ ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**
***10271***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**encorafenib 50 mg capsule, 28**

11937G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9 | 3 | .. | *7034.67 | 30.00 | Braftovi [FB] |

**encorafenib 75 mg capsule, 42**

11938H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 3 | .. | *7034.69 | 30.00 | Braftovi [FB] |

## ▪ ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***6013***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**encorafenib 50 mg capsule, 28**

11954E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 9 | 5 | .. | *7034.67 | 30.00 | Braftovi [FB] |

**encorafenib 75 mg capsule, 42**

11949X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *7034.69 | 30.00 | Braftovi [FB] |

## ▪ VEMURAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***10157***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**vemurafenib 240 mg tablet, 56**

11076Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 3 | .. | *6691.05 | 30.00 | Zelboraf [RO] |

## ▪ VEMURAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6013***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**vemurafenib 240 mg tablet, 56**

11081F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *6691.05 | 30.00 | Zelboraf [RO] |

*Anaplastic lymphoma kinase (ALK) inhibitors*

## ▪ ALECTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**alectinib 150 mg capsule, 4 x 56**

11226W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6482.56 | 30.00 | Alecensa [RO] |

## ▪ BRIGATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**brigatinib 180 mg tablet, 28**

11984R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6815.21 | 30.00 | Alunbrig [TK] |

**brigatinib 90 mg tablet, 28**

11974F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6815.21 | 30.00 | Alunbrig [TK] |

**brigatinib 30 mg tablet, 28**

11980M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 3 | .. | *6815.25 | 30.00 | Alunbrig [TK] |

## ▪ BRIGATINIB

**Caution** Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**

- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack**

11976H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 6815.21 | 30.00 | Alunbrig [TK] |

## ▪ CERITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**ceritinib 150 mg capsule, 3 x 50**

11056X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6934.02 | 30.00 | Zykadia [NV] |

## ▪ CRIZOTINIB

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**crizotinib 200 mg capsule, 60**

10323H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6934.02 | 30.00 | Xalkori [PF] |

**crizotinib 250 mg capsule, 60**

10322G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 6934.02 | 30.00 | Xalkori [PF] |

## ▪ CRIZOTINIB

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**crizotinib 200 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11589Y | 1 | 3 | .. | 6934.02 | 30.00 | Xalkori [PF] |

**crizotinib 250 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11594F | 1 | 3 | .. | 6934.02 | 30.00 | Xalkori [PF] |

## ▪ LORLATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**lorlatinib 25 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12096P | 1 | 3 | .. | 7112.22 | 30.00 | Lorviqua [PF] |

**lorlatinib 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12091J | 1 | 3 | .. | 7112.22 | 30.00 | Lorviqua [PF] |

### *Mitogen-activated protein kinase (MEK) inhibitors*

## ▪ BINIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10328***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition.

**binimetinib 15 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11948W | 2 | 3 | .. | *7396.35 | 30.00 | Mektovi [FB] |

## ▪ BINIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

***10306***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**binimetinib 15 mg tablet, 84**

11961M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *7396.35 | 30.00 | Mektovi [FB] |

## ▪ COBIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10033***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.

**cobimetinib 20 mg tablet, 63**

11074W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7034.64 | 30.00 | Cotellic [RO] |

## ▪ COBIMETINIB

**Note** A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6803***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**cobimetinib 20 mg tablet, 63**

11075X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7034.64 | 30.00 | Cotellic [RO] |

## ▪ TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10051***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.

**trametinib 500 microgram tablet, 30**

10403M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *5684.70 | 30.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

10382K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7525.53 | 30.00 | Mekinist [NV] |

## ▪ TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11821E | 3 | 3 | .. | *5684.70 | 30.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11819C | 1 | 3 | .. | 7525.53 | 30.00 | Mekinist [NV] |

## ▪ TRAMETINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***6752***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10385N | 3 | 5 | .. | *5684.70 | 30.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10405P | 1 | 5 | .. | 7525.53 | 30.00 | Mekinist [NV] |

### *Cyclin-dependent kinase (CDK) inhibitors*

## ▪ ABEMACICLIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**abemaciclib 50 mg tablet, 56**

11876C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Verzenio [LY] |

**abemaciclib 100 mg tablet, 56**

11871T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Verzenio [LY] |

**abemaciclib 150 mg tablet, 56**

11868P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Verzenio [LY] |

## ▪ PALBOCICLIB

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**palbociclib 100 mg tablet, 21**

12819Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Ibrance [PF] |

**palbociclib 125 mg tablet, 21**

12822W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Ibrance [PF] |

**palbociclib 75 mg tablet, 21**

12818P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4249.98 | 30.00 | Ibrance [PF] |

## ▪ RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

**Population criteria:**

- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**ribociclib 200 mg tablet, 21**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11385F | 1 | 5 | .. | 1940.84 | 30.00 | Kisqali [NV] |

## ▪ RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

**ribociclib 200 mg tablet, 63**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11386G | 1 | 5 | .. | 5522.14 | 30.00 | Kisqali [NV] |

## ▪ RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR

- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**

- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**

- Patient must not be premenopausal.

**ribociclib 200 mg tablet, 42**

11397W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3735.47 | 30.00 | Kisqali [NV] |

*Mammalian target of rapamycin (mTOR) kinase inhibitors*

## ▪ EVEROLIMUS

**Authority required (STREAMLINED)**

***7431***

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**everolimus 2.5 mg tablet, 30**

11258M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 457.72 | 30.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

11267B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

11254H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 901.37 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**everolimus 2.5 mg tablet, 30**

2818H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 457.72 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**Population criteria:**

- Patient must be at least 2 years of age.

**everolimus 2 mg dispersible tablet, 30**

11591C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 367.68 | 30.00 | Afinitor [NV] |

**everolimus 3 mg dispersible tablet, 30**

11599L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 547.52 | 30.00 | Afinitor [NV] |

**everolimus 5 mg dispersible tablet, 30**

11592D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 901.16 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***8262***

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**everolimus 2 mg dispersible tablet, 30**

11607X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 367.68 | 30.00 | Afinitor [NV] |

**everolimus 3 mg dispersible tablet, 30**

11608Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 547.52 | 30.00 | Afinitor [NV] |

**everolimus 5 mg dispersible tablet, 30**

11598K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 901.16 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10135K | 1 | 5 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10131F | 1 | 5 | .. | 901.37 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11377T | 1 | 2 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11362B | 1 | 2 | .. | 901.37 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

**Population criteria:**

- Patient must not be pre-menopausal.

**Note** Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2985D | 1 | 5 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2819J | 1 | 5 | .. | 901.37 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 10 mg tablet, 30**

10132G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

10133H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 901.37 | 30.00 | Afinitor [NV] |

## ▪ EVEROLIMUS

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***7432***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 10 mg tablet, 30**

11262R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1737.91 | 30.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

11257L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 901.37 | 30.00 | Afinitor [NV] |

*Human epidermal growth factor receptor 2 (HER2) tyrosine kinase inhibitors*

## ▪ LAPATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***9360***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

**lapatinib 250 mg tablet, 70**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11251E | 2 | 2 | .. | *2933.27 | 30.00 | Tykerb [NV] |

## ▪ LAPATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR
- Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and

(ii) date of last treatment with a taxane and total number of cycles; or

(iii) dates of treatment with trastuzumab and pertuzumab; or

(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or

(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

All reports must be documented in the patient's medical records.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**lapatinib 250 mg tablet, 70**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9148L | 2 | 2 | .. | *2933.27 | 30.00 | Tykerb [NV] |

*Janus-associated kinase (JAK) inhibitors*

## ▪ RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**ruxolitinib 20 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10617T | 1 | 5 | .. | 4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10927D | 1 | 5 | .. | 4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10616R | 2 | 5 | .. | *4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 15 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10615Q | 1 | 5 | .. | 4912.13 | 30.00 | Jakavi [NV] |

## ▪ RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and

(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and

b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and

c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**ruxolitinib 20 mg tablet, 56**

10618W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

10913J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 5 mg tablet, 56**

10614P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 15 mg tablet, 56**

10619X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 4912.13 | 30.00 | Jakavi [NV] |

## ▪ RUXOLITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***13906***

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

The severity of cGVHD is defined by the **National Institutes of Health** (NIH) criteria (Jagasia et al., 2015):

(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1

(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health** (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)**

***13867***

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health** (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority required (STREAMLINED)**

***13866***

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Grandfather treatment (transition from non-PBS-subsidised treatment)

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023, **AND**
- Patient must have received systemic steroid treatment prior to initiation of this drug for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health** (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**ruxolitinib 10 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13235N | 1 | 5 | .. | 4912.13 | 30.00 | Jakavi [NV] |

**ruxolitinib 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13241X | 1 | 5 | .. | 2510.06 | 30.00 | Jakavi [NV] |

*Vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors*

## ▪ AXITINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7433***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**axitinib 1 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10539Q | 2 | 5 | .. | *1070.31 | 30.00 | Inlyta [PF] |

**axitinib 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10556N | 2 | 5 | .. | *4950.13 | 30.00 | Inlyta [PF] |

## ▪ AXITINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

**axitinib 1 mg tablet, 28**

10572K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *1070.31 | 30.00 | Inlyta [PF] |

**axitinib 5 mg tablet, 28**

10540R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *4950.13 | 30.00 | Inlyta [PF] |

*Bruton's tyrosine kinase (BTK) inhibitors*

## ▪ ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time; OR
- Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.

**acalabrutinib 100 mg capsule, 56**

12117R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8219.87 | 30.00 | [a] Calquence [AP] |

**acalabrutinib 100 mg tablet, 56**

13318Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8219.87 | 30.00 | [a] CALQUENCE [AP] |

## ▪ ACALABRUTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**acalabrutinib 100 mg capsule, 56**

12826C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8219.87 | 30.00 | [a] Calquence [AP] |

**acalabrutinib 100 mg tablet, 56**

13325H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8219.87 | 30.00 | [a] CALQUENCE [AP] |

## ▪ IBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time; OR
- Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.

**ibrutinib 140 mg capsule, 90**

11213E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8363.76 | 30.00 | Imbruvica [JC] |

## ▪ IBRUTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**ibrutinib 140 mg capsule, 120**

11419B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 11097.64 | 30.00 | Imbruvica [JC] |

## ▪ ZANUBRUTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Waldenstrom macroglobulinaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; OR
- Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.

**Authority required**

Waldenstrom macroglobulinaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**zanubrutinib 80 mg capsule, 120**

13041J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8795.42 | 30.00 | Brukinsa [IE] |

## ▪ ZANUBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time; OR
- Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent.

**zanubrutinib 80 mg capsule, 120**

13616P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8795.42 | 30.00 | Brukinsa [IE] |

## ▪ ZANUBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

**zanubrutinib 80 mg capsule, 120**

13628G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8795.42 | 30.00 | Brukinsa [IE] |

## ▪ ZANUBRUTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**zanubrutinib 80 mg capsule, 120**

12891L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 8795.42 | 30.00 | Brukinsa [IE] |

*Phosphatidylinositol-3-kinase (Pi3K) inhibitors*

## ▪ IDELALISIB

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***12480***

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**idelalisib 100 mg tablet, 60**

12813J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

12812H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

## ▪ IDELALISIB

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records.

**idelalisib 100 mg tablet, 60**

11171Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

11165P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

## ▪ IDELALISIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR
- The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; OR
- Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**idelalisib 100 mg tablet, 60**

11170X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

11162L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 5118.99 | 30.00 | Zydelig [GI] |

*Other protein kinase inhibitors*

## ▪ CABOZANTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7631***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**cabozantinib 20 mg tablet, 30**

11374P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

11368H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

11367G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

## ▪ CABOZANTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

**Authority required (STREAMLINED)**

***11880***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.

**cabozantinib 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11371L | 1 | 2 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11369J | 1 | 2 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11360X | 1 | 2 | .. | 9962.13 | 30.00 | Cabometyx [IS] |

## ▪ ENTRECTINIB

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**entrectinib 200 mg capsule, 90**

12092K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7290.43 | 30.00 | Rozlytrek [RO] |

## ▪ GILTERITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

**gilteritinib 40 mg tablet, 84**

13093D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25145.13 | 30.00 | Xospata [LL] |

## ▪ GILTERITINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

(a) Leukaemic cells in the CSF; or

(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or

(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or

(d) Extramedullary leukaemia.

**Authority required**

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have relapsed or been refractory prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

(a) Leukaemic cells in the CSF; or

(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or

(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or

(d) Extramedullary leukaemia.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**gilteritinib 40 mg tablet, 84**

13094E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 25145.13 | 30.00 | Xospata [LL] |

## ▪ LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.

**Clinical criteria:**

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

**larotrectinib 100 mg capsule, 56**

| 13043L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 12537.13 | 30.00 | Vitrakvi [BN] |

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

| 13289K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 4287.13 | 30.00 | VITRAKVI [BN] |

**larotrectinib 25 mg capsule, 56**

| 13027P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 3255.88 | 30.00 | Vitrakvi [BN] |

## ▪ LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be/have been under 18 years of age (i.e. prior to their 18$^{th}$ birthday) at treatment initiation with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**

- The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date), **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**larotrectinib 100 mg capsule, 56**

13031W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 12537.13 | 30.00 | Vitrakvi [BN] |

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

13281B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4287.13 | 30.00 | VITRAKVI [BN] |

**larotrectinib 25 mg capsule, 56**

13029R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3255.88 | 30.00 | Vitrakvi [BN] |

## ▪ LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***11168***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

**Authority required (STREAMLINED)**

***8584***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**lenvatinib 4 mg capsule, 30**

11638M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 2 | .. | *7662.15 | 30.00 | Lenvima [EI] |

## ▪ LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***6604***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

**Authority required (STREAMLINED)**

***6578***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**lenvatinib 10 mg capsule, 30**

10965D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5162.13 | 30.00 | Lenvima [EI] |

**lenvatinib 4 mg capsule, 30**

10952K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 2626.04 | 30.00 | Lenvima [EI] |

## ▪ LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***13921***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-

renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

**Authority required (STREAMLINED)**

***13972***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

**Authority required (STREAMLINED)**

***14007***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements

**Clinical criteria:**

- Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023, **AND**
- Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented, **AND**
- The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

### lenvatinib 4 mg capsule, 30

13252L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5144.09 | 30.00 | Lenvima [EI] |

## ▪ LENVATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***14042***
Advanced, metastatic or recurrent endometrial carcinoma
Treatment Phase: Initial treatment
**Clinical criteria:**
- Patient must have received prior treatment with platinum-based chemotherapy, **AND**
- The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

**Treatment criteria:**
- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Authority required (STREAMLINED)**
***14041***
Advanced, metastatic or recurrent endometrial carcinoma
Treatment Phase: Continuing treatment
**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**
- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

**Authority required (STREAMLINED)**
***14043***
Advanced, metastatic or recurrent endometrial carcinoma
Treatment Phase: Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements
**Clinical criteria:**
- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023, **AND**
- The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.
**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**lenvatinib 10 mg capsule, 30**

13283D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5162.13 | 30.00 | Lenvima [EI] |

**lenvatinib 4 mg capsule, 30**

13290L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5144.09 | 30.00 | Lenvima [EI] |

## ▪ LENVATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
***13921***
Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

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**Authority required (STREAMLINED)**

***13972***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

**Authority required (STREAMLINED)**

***14007***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements

**Clinical criteria:**

- Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023, **AND**
- Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented, **AND**
- The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemoglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal

(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**lenvatinib 10 mg capsule, 30**

13253M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5162.13 | 30.00 | Lenvima [EI] |

## ▪ NINTEDANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nintedanib 100 mg capsule, 60**

11100F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1679.59 | 30.00 | Ofev [BY] |

**nintedanib 150 mg capsule, 60**

11106M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3237.85 | 30.00 | Ofev [BY] |

## ▪ NINTEDANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Progressive fibrosing Interstitial lung disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication, **AND**
- The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5), **AND**
- Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted**,** adjusted for each of: (i) age, (ii) gender, (iii) height, **AND**
- The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted, **AND**

- The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is), **AND**
- The condition must not be due to reversible causes (e.g. drug toxicity).

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

**Note** Interstitial lung disease includes, but is not limited to:
(i) connective tissue associated interstitial lung disease;
(ii) chronic fibrosing hypersensitivity pneumonitis;
(iii) idiopathic non-specific interstitial pneumonia;
(iv) pulmonary sarcoidosis.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Progressive fibrosing Interstitial lung disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nintedanib 100 mg capsule, 60**

12967L

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | | 5 | .. | 1679.59 | 30.00 | Ofev [BY] |

**nintedanib 150 mg capsule, 60**

12953R

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | | 5 | .. | 3237.85 | 30.00 | Ofev [BY] |

## ▪ PAZOPANIB

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

***11939***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 30**

2232L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1137.38 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 30**

2201W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2205.07 | 30.00 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***9247***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:
adipocytic soft tissue sarcoma;
gastrointestinal stromal tumour (GIST);
rhabdomyosarcoma other than alveolar or pleomorphic;
chondrosarcoma;
osteosarcoma;
Ewings tumour/primitive neuroectodermal tumour;
dermofibromatosis sarcoma protuberans;
inflammatory myofibroblastic sarcoma;
malignant mesothelioma;
mixed mesodermal tumour of the uterus.

**pazopanib 200 mg tablet, 90**

10042M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3226.54 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 60**

10041L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 4248.01 | 30.00 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7458***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**pazopanib 200 mg tablet, 90**

10047T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3226.54 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 60**

10043N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 4248.01 | 30.00 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7459***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**pazopanib 200 mg tablet, 30**

10054E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1137.38 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 30**

10052C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2205.07 | 30.00 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

***11937***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11252F | 1 | 5 | .. | 3226.54 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11261Q | 1 | 5 | .. | 4248.01 | 30.00 | Votrient [NV] |

## ▪ PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required (STREAMLINED)**

***11974***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2029T | 1 | 2 | .. | 3226.54 | 30.00 | Votrient [NV] |

**pazopanib 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2030W | 1 | 2 | .. | 4248.01 | 30.00 | Votrient [NV] |

## ▪ RIPRETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; OR
- The condition must have progressed despite each of: (i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug for the first time - retreatment/continuing treatment beyond the available repeat prescription is not permitted under this listing; see 'Continuing treatment' Treatment Phase listing to continue PBS-subsidised treatment in a patient without disease progression.

**Note** Currently PBS-listed drugs with the indication of: 'metastatic or unresectable malignant gastrointestinal stromal tumour' are: imatinib and sunitinib

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**ripretinib 50 mg tablet, 90**

12764T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 16304.07 | 30.00 | Qinlock [TS] |

## ▪ SORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

10226F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *5557.79 | 30.00 | Nexavar [BN] |

## ▪ SORAFENIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***7487***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

10242C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *5557.79 | 30.00 | Nexavar [BN] |

## ▪ SORAFENIB

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.
Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***11160***

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

**Authority required (STREAMLINED)**
***8617***
Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**sorafenib 200 mg tablet, 60**

| 9380Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *5557.79 | 30.00 | Nexavar [BN] |

## ▪ SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.
Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.
Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**sunitinib 12.5 mg capsule, 28**

| 10004M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

| 2959R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 2837H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

| 10464R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
***7471***
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**

- The treatment must be as monotherapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sunitinib 12.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10009T | 1 | 5 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2842N | 1 | 5 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10010W | 1 | 5 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10473F | 1 | 5 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

***11875***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**sunitinib 12.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9420T | 1 | 3 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9421W | 1 | 3 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9422X | 1 | 3 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10459L | 1 | 3 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ SUNITINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

**sunitinib 12.5 mg capsule, 28**

9488J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

9489K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

9490L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

10503T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Authority required (STREAMLINED)**

***11878***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**sunitinib 12.5 mg capsule, 28**

9417P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

| 9418Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 9419R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

| 10504W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ SUNITINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)**

***13153***

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**sunitinib 12.5 mg capsule, 28**

| 11266Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 806.47 | 30.00 | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 25 mg capsule, 28**

| 11253G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 1559.47 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 50 mg capsule, 28**

| 11250D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 3044.20 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

**sunitinib 37.5 mg capsule, 28**

| 11256K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | .. | 2295.52 | 30.00 | [a] ARX-Sunitinib [XT]<br>[a] Sunitinib Sandoz [SZ] | [a] Sunitinib MSN [LR]<br>[a] Sutent [PF] |

## ▪ TEPOTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***13434***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of MET exon 14 skipping alterations in tumour material.

**Authority required (STREAMLINED)**

***13441***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

***13435***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2022, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have evidence of MET exon 14 skipping alterations in tumour material.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**tepotinib 225 mg tablet, 60**

13171F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9104.33 | 30.00 | Tepmetko [SG] |

## MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

*CD38 (Clusters of Differentiation 38) inhibitors*

### ▪ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

**Treatment criteria:**

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12683M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 8 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

## ▪ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12725R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

## ▪ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12755H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

## ▪ DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

13199Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

## ▪ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 3 months after the date specified in the clinical criteria.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in

combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug, **AND**

- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12704P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 7 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

## ▪ DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
PBS Authorities
GPO Box 9826
[Your capital city]

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Initial treatment from week 0 to week 24

**Clinical criteria:**

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

**Treatment criteria:**

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023, **AND**
- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.

**Treatment criteria:**

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information, **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Determine an appropriate number of repeat prescriptions for this authority application in line with either:

(i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or

(ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

13202W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 15 | .. | 7172.41 | 30.00 | Darzalex SC [JC] |

*HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors*

## ▪ TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10212***

Early HER2 positive breast cancer

Treatment Phase: 3 weekly treatment regimen

**Clinical criteria:**

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10682F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1608.57 | 30.00 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***9353***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10798H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1608.57 | 30.00 | Herceptin SC [RO] |

## ▪ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***9462***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10803N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1608.57 | 30.00 | Herceptin SC [RO] |

# OTHER ANTINEOPLASTIC AGENTS

*Histone deacetylase (HDAC) inhibitors*

## ▪ VORINOSTAT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**vorinostat 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11138F | 1 | 2 | .. | 4249.14 | 30.00 | Zolinza [MK] |

## ▪ VORINOSTAT

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**vorinostat 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11141J | 1 | 1 | .. | 4249.14 | 30.00 | Zolinza [MK] |

*Hedgehog pathway inhibitors*

## ▪ SONIDEGIB

**Caution** Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**sonidegib 200 mg capsule, 30**

11304Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7592.49 | 30.00 | Odomzo [RA] |

## ▪ VISMODEGIB

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vismodegib 150 mg capsule, 28**

11070P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 7097.13 | 30.00 | Erivedge [RO] |

*Poly (ADP-ribose) polymerase (PARP) inhibitors*

## ▪ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - first line treatment of a patient requiring a daily dose of 3 capsules

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**niraparib 100 mg capsule, 84**

13079J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9874.39 | 30.00 | Zejula [GK] |

## ▪ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**niraparib 100 mg capsule, 56**

13112D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6636.97 | 30.00 | Zejula [GK] |

## ▪ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**niraparib 100 mg capsule, 56**

13089X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6636.97 | 30.00 | Zejula [GK] |

## ▪ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment of a patient requiring a daily dose of 3 capsules

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**niraparib 100 mg capsule, 84**

13092C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 9874.39 | 30.00 | Zejula [GK] |

## ▪ OLAPARIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10937***

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - second line treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug as a second line therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

**olaparib 100 mg tablet, 56**

11503K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

11539H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - second line treatment

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**olaparib 100 mg tablet, 56**

11522K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

11528R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - first line treatment

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12169L | 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12161C | 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12170M | 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12157W | 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12921C | 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12913P | 2 | 5 | .. | *6631.63 | 30.00 | Lynparza [AP] |

## ▪ OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for the first time.

**olaparib 100 mg tablet, 56**

12932P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

12929L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *6631.63 | 30.00 | Lynparza [AP] |

*Other antineoplastic agents*

## ▪ HYDROXYCARBAMIDE (HYDROXYUREA)

**hydroxycarbamide (hydroxyurea) 500 mg capsule, 100**

3093T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 51.78 | 30.00 | [a] Hydrea [LM] | [a] HYDROXYCARBAMIDE MEDSURGE [DZ] |

## ▪ VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment under this restriction with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

11639N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7785.15 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

**Clinical criteria:**

- The treatment must be for dose titration purposes.

**venetoclax 10 mg tablet, 2**

12999E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 7 | .. | .. | *108.68 | 30.00 | Venclexta [VE] |

**venetoclax 50 mg tablet, 7**

11648C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 255.66 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

12199C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 7785.15 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

**venetoclax 100 mg tablet, 120**

12205J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 7785.15 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

**Clinical criteria:**

- The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis), **AND**
- Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug, **AND**
- The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses), **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

**venetoclax 100 mg tablet, 120**

12803W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 7785.15 | 30.00 | Venclexta [VE] |

**venetoclax 50 mg tablet, 7**

12773G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 2 | .. | *998.69 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Dose titration occurring at the start of treatment for relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

**Treatment criteria:**

- Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression.

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

11630D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 1792.40 | 30.00 | Venclexta [VE] |

## ▪ VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:
(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.
See the following literature reference for details:
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

12188L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 1792.40 | 30.00 | Venclexta [VE] |

# ▪ ENDOCRINE THERAPY

## HORMONES AND RELATED AGENTS

*Progestogens*

## ▪ MEDROXYPROGESTERONE

**Restricted benefit**

Advanced breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**medroxyprogesterone acetate 500 mg tablet, 30**

2728N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 98.69 | 30.00 | Provera [PF] |

## ▪ MEDROXYPROGESTERONE

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Restricted benefit**

Endometrial cancer

**medroxyprogesterone acetate 100 mg tablet, 100**

2725K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 73.02 | 30.00 | Provera [PF] |

**medroxyprogesterone acetate 200 mg tablet, 60**

2316X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 81.28 | 30.00 | Provera [PF] |

**medroxyprogesterone acetate 250 mg tablet, 60**

2727M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 98.69 | 30.00 | Provera [PF] |

*Gonadotropin releasing hormone analogues*

## ▪ GOSERELIN

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**goserelin 10.8 mg implant, 1**

8093Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 714.09 | 30.00 | Zoladex 10.8 Implant [AP] |

## ▪ GOSERELIN

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**Restricted benefit**

Endometriosis

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

**Note** Only 1 course of not more than 6 months' therapy will be authorised.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Restricted benefit**

Anticipated premature ovarian failure

**Clinical criteria:**

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

**Population criteria:**

- Patient must be pre-menopausal.

**goserelin 3.6 mg implant, 1**

1454M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 212.70 | 30.00 | Zoladex Implant [AP] |

## ▪ GOSERELIN (&) BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28], 1 pack**

9065D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 1042.78 | 30.00 | ZolaCos CP 10.8/50(28) [AP] |

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84], 1 pack**

9066E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 1322.45 | 30.00 | ZolaCos CP 10.8/50(84) [AP] |

**goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack**

9064C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 413.24 | 30.00 | ZolaCos CP 3.6/50 [AP] |

## ▪ LEUPRORELIN

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**leuprorelin acetate 45 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11943N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1376.71 | 30.00 | Lucrin Depot 6-Month [VE] |

**leuprorelin acetate 22.5 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

8876E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 714.09 | 30.00 | Lucrin Depot 3 Month PDS [VE] |

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

8877F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 940.06 | 30.00 | Lucrin Depot 4 Month PDS [VE] |

**leuprorelin acetate 7.5 mg modified release injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber syringe**

8875D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 270.53 | 30.00 | Lucrin Depot 7.5mg PDS [VE] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8708H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 714.09 | 30.00 | Eligard 3 month [MF] |

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8709J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 940.06 | 30.00 | Eligard 4 month [MF] |

**leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8859G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1376.71 | 30.00 | Eligard 6 month [MF] |

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8707G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 270.53 | 30.00 | Eligard 1 month [MF] |

## ▪ LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11944P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 713.25 | 30.00 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## ▪ LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10th birthday if female; OR
- Patient must be of an age that is prior to their 11th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11960L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 713.25 | 30.00 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## ▪ LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10th birthday if female; OR
- Patient must be of an age that is prior to their 11th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

13187C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1376.71 | 30.00 | Eligard 6 month [MF] |

## ▪ LEUPRORELIN (&) BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10962Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 417.29 | 30.00 | Bi ELIGARD CP [MF] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10963B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 976.24 | 30.00 | Bi ELIGARD CP [MF] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

10969H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 1109.24 | 30.00 | Bi ELIGARD CP [MF] |

## ▪ TRIPTORELIN

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

9379P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 953.61 | 30.00 | Diphereline [IS] |

**triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

9378N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 363.31 | 30.00 | Diphereline [IS] |

## ▪ TRIPTORELIN

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 12th birthday if female; OR
- Patient must be of an age that is prior to their 13th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male.

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

5297T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1818.05 | 30.00 | Diphereline [IS] |

# HORMONE ANTAGONISTS AND RELATED AGENTS

*Anti-estrogens*

## ▪ FULVESTRANT

**Authority required (STREAMLINED)**

***11473***

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable.

**Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes**

12300J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 262.01 | 30.00 | [a] FULVESTRANT ACCORD [OC]<br>[a] Fulvestrant Sandoz [SZ] | [a] FULVESTRANT EVER PHARMA [IT] |

## ▪ TAMOXIFEN

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

1880Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | [B]6.94 | *33.41 | 27.87 | [a] Nolvadex-D [AP] |

## ▪ TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 60**

2110C

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.47 | 27.87 | [a] Genox 20 [AF]<br>[a] Tamosin [OX] | [a] GenRx Tamoxifen [GX]<br>[a] Tamoxifen Sandoz [SZ] |

## ▪ TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Reduction of breast cancer risk

**Clinical criteria:**

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

**tamoxifen 20 mg tablet, 30**

10911G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 19.73 | 21.13 | [a] Genox 20 [AF] |
| | | [B]3.47 | 23.20 | 21.13 | [a] Nolvadex-D [AP] |

## ▪ TOREMIFENE

**toremifene 60 mg tablet, 30**

8216K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 51.65 | 30.00 | Fareston [OX] |

*Anti-androgens*

## ▪ APALUTAMIDE

**Note** Special Pricing Arrangements apply.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Authority required**

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**apalutamide 60 mg tablet, 120**

12992T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3715.43 | 30.00 | Erlyand [JC] |

## ▪ APALUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**apalutamide 60 mg tablet, 120**

13288J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3715.43 | 30.00 | Erlyand [JC] |

## ▪ BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5729***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**bicalutamide 50 mg tablet, 28**

8094B (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 52.07 | 30.00 | [a] APO-Bicalutamide [TX]<br>[a] Calutex [AS]<br>[a] Cosudex [AP] | [a] Bicalox [ZS]<br>[a] Cosamide 50 [AF] |

## ▪ CYPROTERONE

**cyproterone acetate 100 mg tablet, 50**

8019C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 60.80 | 30.00 | [a] ANTERONE 100 [RW]<br>[a] Cyprone 100 [AF]<br>[a] GenRx Cyproterone Acetate [GX] | [a] APO-Cyproterone [TX]<br>[a] Cyproterone Sandoz [HX]<br>[a] Pharmacor Cyproterone 100 [CR] |
| | | [B]1.21 | 62.01 | 30.00 | [a] Androcur-100 [BN] | |

**cyproterone acetate 50 mg tablet, 50**

1270W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *74.39 | 30.00 | [a] ANTERONE 50 [RW]<br>[a] Cyprone 50 [AL]<br>[a] GenRx Cyproterone Acetate [GX] | [a] APO-Cyproterone [TX]<br>[a] Cyproterone Sandoz [HX]<br>[a] Pharmacor Cyproterone 50 [CR] |
| | | [B]1.96 | *76.35 | 30.00 | [a] Androcur [BN] | |

## ▪ DAROLUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**darolutamide 300 mg tablet, 112**

12684N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3537.77 | 30.00 | Nubeqa [BN] |

## ▪ ENZALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**enzalutamide 40 mg capsule, 112**

10174L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3478.58 | 30.00 | Xtandi [LL] |

## ▪ ENZALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**enzalutamide 40 mg capsule, 112**

13118K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3478.58 | 30.00 | Xtandi [LL] |

## ▪ ENZALUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**enzalutamide 40 mg capsule, 112**

13353T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 3478.58 | 30.00 | Xtandi [LL] |

## ▪ FLUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5816***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 100**

1417N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 175.23 | 30.00 | Flutamin [AF] |

*Aromatase inhibitors*

## ▪ ANASTROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

8179L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 22.92 | 24.32 | [a] Anastrozole GH [GQ]<br>[a] APO-Anastrozole [TX] | [a] Anastrozole Sandoz [SZ]<br>[a] Arianna 1 [AF] |
| | | [B]4.05 | 26.97 | 24.32 | [a] Arimidex [AP] | |

## ▪ EXEMESTANE

**Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**exemestane 25 mg tablet, 30**

10103R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 58.42 | 30.00 | [a] APO-Exemestane [TX]<br>[a] Exemestane Sandoz [SZ] | [a] Exemestane GH [GQ] |
| | | [B]3.28 | 61.70 | 30.00 | [a] Aromasin [PF] | |

## ▪ EXEMESTANE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**exemestane 25 mg tablet, 30**

8506Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 58.42 | 30.00 | [a] APO-Exemestane [TX] | [a] Exemestane GH [GQ] |
| | | | | | [a] Exemestane Sandoz [SZ] | |
| | | [B]3.28 | 61.70 | 30.00 | [a] Aromasin [PF] | |

## ▪ LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**letrozole 2.5 mg tablet, 30**

8245Y (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 27.91 | 29.31 | [a] Femolet [AF] | [a] Gynotril [ZS] |
| | | | | | [a] Letrozole APOTEX [GX] | [a] Letrozole GH [HQ] |
| | | | | | [a] Letrozole Sandoz [SZ] | [a] Pharmacor Letrozole 2.5 [CR] |
| | | [B]3.77 | 31.68 | 29.31 | [a] Femara 2.5 mg [NV] | |

*Other hormone antagonists and related agents*

## ▪ ABIRATERONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 250 mg tablet, 120**

2698B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3442.99 | 30.00 | Zytiga [JC] |

**abiraterone acetate 500 mg tablet, 60**

11206T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3442.99 | 30.00 | Zytiga [JC] |

## ▪ ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

13263C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 1359.77 | 30.00 | Yonsa Mpred [RA] |

## ▪ DEGARELIX

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

2784M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 363.31 | 30.00 | Firmagon 80mg [FP] |

## ▪ DEGARELIX

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack**

2785N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 379.92 | 30.00 | Firmagon 120mg [FP] |

# ▪ IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

*Interferons*

## ▪ INTERFERON BETA-1B

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***7695***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack**

8101J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 763.07 | 30.00 | Betaferon [BN] |

## ▪ PEGINTERFERON ALFA-2A

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11416W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 601.95 | 30.00 | Pegasys [XO] |

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11037X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 695.86 | 30.00 | Pegasys [XO] |

## ▪ PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***7695***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices**

10212L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 668.10 | 30.00 | Plegridy [BD] |

**peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack**

10218T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 668.10 | 30.00 | Plegridy [BD] |

## ▪ PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices**

10220X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 668.10 | 30.00 | Plegridy [BD] |

*Other immunostimulants*

## ▪ GLATIRAMER ACETATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL syringes and pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL pen devices are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***7695***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***6860***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices**

13110B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | [B]7.99 | 676.09 | 30.00 | [a] Copaxone [TB] |

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes**

10416F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 628.59 | 30.00 | [a] Copaxone [TB]<br>[a] GLATIRAMER ACETATE-TEVA [EV] | [a] Glatira [JU] |

## ▪ MYCOBACTERIUM BOVIS BCG DANISH STRAIN

**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials**

12931N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡3 | 1 | .. | *1447.71 | 30.00 | VesiCulture [LM] |

## ▪ MYCOBACTERIUM BOVIS BCG TICE STRAIN

**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials**

1131M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 459.00 | 30.00 | OncoTICE [MK] |

# ▪ IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

*Selective immunosuppressants*

## ▪ ABATACEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a

treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### abatacept 125 mg/mL injection, 4 x 1 mL pen devices

11684Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 946.49 | 30.00 | Orencia ClickJect [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1221G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 946.49 | 30.00 | Orencia [BQ] |

## ▪ ABATACEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

11693K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 946.49 | 30.00 | Orencia ClickJect [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1220F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 946.49 | 30.00 | Orencia [BQ] |

## ▪ APREMILAST

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***13243***

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must have failed to achieve an adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; OR
- Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types.

**Population criteria:**

- Patient must be at least 18 years of age.

**apremilast 30 mg tablet, 56**

12223H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 653.71 | 30.00 | Otezla [AN] |

**apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27**

12218C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 273.20 | 30.00 | Otezla [AN] |

## ▪ BARICITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**baricitinib 2 mg tablet, 28**

11442F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Olumiant [LY] |

**baricitinib 4 mg tablet, 28**

11443G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Olumiant [LY] |

## ▪ BARICITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**baricitinib 2 mg tablet, 28**

11437Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1272.31 | 30.00 | Olumiant [LY] |

**baricitinib 4 mg tablet, 28**

11447L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1272.31 | 30.00 | Olumiant [LY] |

## ▪ CLADRIBINE

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10170***

Relapsing remitting multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**Authority required (STREAMLINED)**

***10171***

Relapsing remitting multiple sclerosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**cladribine 10 mg tablet, 1**

11603Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 3803.52 | 30.00 | Mavenclad [SG] |

**cladribine 10 mg tablet, 4**

11604R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *29293.25 | 30.00 | Mavenclad [SG] |

**cladribine 10 mg tablet, 6**

11611D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 22010.47 | 30.00 | Mavenclad [SG] |

## ▪ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**everolimus 250 microgram tablet, 60**

8840G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 201.24 | 30.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 500 microgram tablet, 60**

8841H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 385.90 | 30.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 750 microgram tablet, 60**

8842J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 3 | .. | *1119.25 | 30.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 1 mg tablet, 60**

9352F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 3 | .. | *1470.73 | 30.00 | [a] Certican [NV] | [a] Everocan [CR] |

## ▪ FINGOLIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10198***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Population criteria:**

- Patient must weigh 40 kg or less.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***10093***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Population criteria:**

- Patient must weigh 40 kg or less.

**fingolimod 250 microgram capsule, 28**

11818B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1063.44 | 30.00 | Gilenya [NV] |

## ▪ FINGOLIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10162***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***10172***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**fingolimod 500 microgram capsule, 28**

5262Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 1063.44 | 30.00 | [a] AKM Fingolimod [RW] | [a] Fingolimod Sandoz [SZ] |
| | | | | | [a] Fingolimod SUN [RA] | [a] Fingolimod-Teva [TB] |
| | | | | | [a] FINGOLIS [LR] | [a] Fynod [AF] |
| | | | | | [a] Gilenya [NV] | [a] Pharmacor Fingolimod [CR] |

## ▪ LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

5449T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.44 | 30.00 | [a] Arabloc [AV] | [a] Arava [SW] |
| | | | | | [a] Ataris 10 [AF] | [a] Leflunomide APOTEX [GX] |
| | | | | | [a] Leflunomide generichealth [HQ] | [a] Leflunomide Sandoz [SZ] |

**leflunomide 20 mg tablet, 30**

5450W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 38.04 | 30.00 | [a] Arava [SW] | [a] Ataris 20 [AF] |
| | | | | | [a] Leflunomide APOTEX [GX] | [a] Leflunomide generichealth [HQ] |
| | | | | | [a] Leflunomide Sandoz [SZ] | |

## ▪ LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

| 8374R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 29.44 | 30.00 | [a] Arabloc [AV]<br>[a] Ataris 10 [AF]<br>[a] Leflunomide generichealth [HQ]<br>[a] Lunava 10 [RW] | [a] Arava [SW]<br>[a] Leflunomide APOTEX [GX]<br>[a] Leflunomide Sandoz [SZ] |

**leflunomide 20 mg tablet, 30**

| 8375T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 38.04 | 30.00 | [a] Arava [SW]<br>[a] Leflunomide APOTEX [GX]<br>[a] Leflunomide Sandoz [SZ] | [a] Ataris 20 [AF]<br>[a] Leflunomide generichealth [HQ]<br>[a] Lunava 20 [RW] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**mycophenolate 180 mg enteric tablet, 120**

| 2150E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 105.23 | 30.00 | Myfortic [NV] |

**mycophenolate 360 mg enteric tablet, 120**

| 2193K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 201.67 | 30.00 | Myfortic [NV] |

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

| 8651H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | #287.10 | 30.00 | [a] CellCept [RO] | [a] Pharmacor Mycophenolate [CR] |

**mycophenolate mofetil 500 mg tablet, 50**

| 8650G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *118.86 | 30.00 | [a] CellCept [RO]<br>[a] MycoCept [RF]<br>[a] Mycophenolate GH [GQ]<br>[a] Noumed Mycophenolate [VO] | [a] Ceptolate [AF]<br>[a] Mycophenolate APOTEX [GX]<br>[a] Mycophenolate Sandoz [SZ]<br>[a] Pharmacor Mycophenolate 500 [CR] |

## ▪ MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**mycophenolate mofetil 250 mg capsule, 50**

| 1836P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | .. | *118.95 | 30.00 | [a] Ceptolate [AF] |

**mycophenolate mofetil 250 mg capsule, 100**

| 8649F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 5 | .. | *118.92 | 30.00 | [a] APO-Mycophenolate [TX]<br>[a] Mycophenolate Sandoz [SZ] | [a] CellCept [RO]<br>[a] Pharmacor Mycophenolate 250 [CR] |

## ▪ OFATUMUMAB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10172***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**

- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

12641H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2184.33 | 30.00 | Kesimpta [NV] |

## ▪ OFATUMUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** The intent of this listing is to provide doses at weeks 0, 1 and 2. For treatment at week 4 and beyond, see the 'Continuing treatment' listing.

**Authority required (STREAMLINED)**

***10162***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

12642J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *6337.02 | 30.00 | Kesimpta [NV] |

## ▪ OZANIMOD

**Note** Ensure that PBS-subsidy is approved for the 920 mcg strength prior to supply of this titration pack. It is advisable to only have the titration pack prescription dispensed at the same time as a prescription for the 920 mcg capsules, or where a supply of the 920 mcg capsules is already in existence (in the case of mid treatment dose interruption).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14017***

Moderate to severe ulcerative colitis

Treatment Phase: Dose escalation occurring at initial treatment or re-initiation of treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7**

13251K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 588.92 | 30.00 | Zeposia [CJ] |

## ▪ OZANIMOD

**Note** The initiation pack is intended for use at the commencement of treatment and for re-initiation of therapy following treatment interruption. The first prescription for the 920 microgram capsules should occur under the Initial treatment restriction. Subsequent prescriptions should then occur under the Continuing treatment restriction. If treatment interruption of more than 14 consecutive days occurs for reasons other than lack of efficacy, apply under the Continuing treatment restriction for each of the Initiation pack and 920 microgram capsules. If treatment interruption occurs within the first 14 days, or, for more than 7 consecutive doses between treatment Days 15 to 28, re-apply for an initiation pack under the 'Initial treatment' treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10162***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***10172***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**ozanimod 920 microgram capsule, 28**

12271W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2220.42 | 30.00 | Zeposia [CJ] |

**ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7**

12278F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 588.92 | 30.00 | Zeposia [CJ] |

## ▪ OZANIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation, **AND**
- The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;

(ii) the date of commencement of this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ozanimod 920 microgram capsule, 28**

13269J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2220.42 | 30.00 | Zeposia [CJ] |

## ▪ OZANIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ozanimod 920 microgram capsule, 28

13271L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2220.42 | 30.00 | Zeposia [CJ] |

## ▪ SIPONIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***10955***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory**,** with**/**without assistance**/**support, **AND**
- Patient must have mild disability in at least 3 functional systems; OR
- Patient must have moderate disability in at least 1 functional system.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.

**Note** There is no specific Medical Benefits Schedule item for CYP2C9 metabolising enzyme status testing.

**Authority required (STREAMLINED)**

***10953***

Multiple sclerosis

Treatment Phase: Continuing treatment (including recommencement of treatment)

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory**,** with**/**without assistance**/**support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**siponimod 250 microgram tablet, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12172P | 1 | .. | .. | 240.37 | 30.00 | Mayzent [NV] |

**siponimod 250 microgram tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12160B | 1 | 5 | .. | 2220.43 | 30.00 | Mayzent [NV] |

**siponimod 2 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12158X | 1 | 5 | .. | 2220.42 | 30.00 | Mayzent [NV] |

## ▪ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**sirolimus 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8984W | 1 | 3 | .. | 339.64 | 30.00 | Rapamune [PF] |

**sirolimus 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8724E | 1 | 3 | .. | 671.28 | 30.00 | Rapamune [PF] |

**sirolimus 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8833X | 1 | 3 | .. | 1298.65 | 30.00 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8725F | ‡1 | 3 | .. | 529.58 | 30.00 | Rapamune [PF] |

## ▪ TERIFLUNOMIDE

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10150***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***10199***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**teriflunomide 14 mg tablet, 28**

2898M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 245.67 | 30.00 | [a] APO-TERIFLUNOMIDE [TX] | [a] Pharmacor Teriflunomide [CR] |
| | | | | | [a] TERIFLAGIO [RW] | [a] Teriflunomide Dr.Reddy's [RZ] |
| | | | | | [a] Teriflunomide GH [GQ] | [a] Teriflunomide Sandoz [SZ] |
| | | | | | [a] Terimide [AF] | |

## ▪ TOFACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and

measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

10511F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

## ▪ TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the

new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level

respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

11675L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

## ▪ TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under the Balance of supply restriction to complete up to 24 weeks continuing treatment.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under this restriction to complete up to 24 weeks continuing treatment.

**tofacitinib 5 mg tablet, 56**

12557X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

**tofacitinib 10 mg tablet, 56**

12589N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1980.48 | 30.00 | Xeljanz [PF] |

## ▪ TOFACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20

mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
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HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

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| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to

prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
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HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

12556W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

**tofacitinib 10 mg tablet, 56**

12588M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1980.48 | 30.00 | Xeljanz [PF] |

## ▪ TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

13349N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

## ▪ TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023, **AND**
- Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tofacitinib 5 mg tablet, 56**

13345J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1211.93 | 30.00 | Xeljanz [PF] |

## ▪ UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands

**Treatment criteria:**

- Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions, **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true: (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled', **AND**
- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**upadacitinib 30 mg modified release tablet, 28**

12827D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2077.29 | 30.00 | Rinvoq [VE] |

**upadacitinib 15 mg modified release tablet, 28**

12835M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any further authority applications occurring immediately after access through this dose modification listing are not to occur through any of the following Treatment phase listings: (i) Balance of Supply, (ii) Initial Treatment.

**Note Dose modification**
Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Dose modification

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy.

**upadacitinib 30 mg modified release tablet, 28**

13265E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 2077.29 | 30.00 | Rinvoq [VE] |

**upadacitinib 15 mg modified release tablet, 28**

13256Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are

not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

11979L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

12621G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

12648Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has

failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.
Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have commenced treatment with this biological medicine for this condition prior to 1 August 2023, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**upadacitinib 15 mg modified release tablet, 28**

13343G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:
Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.
Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:
https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:
Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94
The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**

- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**upadacitinib 30 mg modified release tablet, 28**

12836N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 2077.29 | 30.00 | Rinvoq [VE] |

**upadacitinib 15 mg modified release tablet, 28**

12828E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:
Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.
Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:
Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94
The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

**upadacitinib 30 mg modified release tablet, 28**

12829F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2077.29 | 30.00 | Rinvoq [VE] |

**upadacitinib 15 mg modified release tablet, 28**

12831H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose strength change is required, see 'Dose modification' treatment phase to continue treatment at a new dose strength.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation, **AND**
- The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;

(ii) the date of commencement of this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance of 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 30 mg modified release tablet, 28**

13249H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2077.29 | 30.00 | Rinvoq [VE] |

**upadacitinib 15 mg modified release tablet, 28**

13250J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment

attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**

- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

13350P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ UPADACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under

'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
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HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

11989B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 3 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than

5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR

- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

12624K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 3 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient - untreated with biological medicine)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 45 mg modified release tablet, 28**

13262B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 2716.98 | 30.00 | Rinvoq [VE] |

## ▪ UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**

- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

12625L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1272.31 | 30.00 | Rinvoq [VE] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one

time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12620F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1747.30 | 30.00 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have

completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment with subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12638E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1747.30 | 30.00 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12644L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1747.30 | 30.00 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12647P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1747.30 | 30.00 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12639F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1747.30 | 30.00 | Entyvio [TK] |

## ▪ VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in

therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for

permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12654B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1747.30 | 30.00 | Entyvio [TK] |

*Tumor necrosis factor alpha (TNF-alpha) inhibitors*

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4

weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10399H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12379M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10400J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12411F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11529***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12330Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *1646.05 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13221W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1345.59 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12449F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *1345.59 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12395J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *1345.59 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12448E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1345.59 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12408C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *1345.59 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11718***

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**

- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12436M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *864.91 | 30.00 | Amgevita [XT] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10412B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12413H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further

details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10420K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12341M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised

adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11634***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12327T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13208E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must

be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11634***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12328W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13226D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological

medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11631***

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.
If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12352D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13225C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine

therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11524***

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12353E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13230H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11604***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12365T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13209F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient

is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11524***

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12367X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13220T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under

these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9191R | 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12389C | 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the

age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11604***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12401Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13223Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12410E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11523***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12415K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13214L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with

respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11718***

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12420Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13224B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine

therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11718***

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12434K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13218Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity

of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11631***

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12437N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13219R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11523***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12438P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13216N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.
Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have

failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11579***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12351C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *864.91 | 30.00 | Amgevita [XT] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy

of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12423W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 706.70 | 30.00 | [a] Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12354F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *864.91 | 30.00 | [a] Amgevita [XT] |

## ▪ ADALIMUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12385W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | .. | *1646.05 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12383R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | .. | *1345.59 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR

- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (recommencement of treatment)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12450G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12524E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy

of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11579***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12325Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13213K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11605***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12326R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13222X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response

must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11605***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12329X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13227E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3

biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and

Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***11579***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12334E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13211H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11635***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

***11606***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12366W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13217P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and

wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required (STREAMLINED)**

***11635***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

***11606***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12403T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13215M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12424X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 706.70 | 30.00 | [a] Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12440R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *864.91 | 30.00 | [a] Amgevita [XT] |

## ▪ ADALIMUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12369B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *1646.05 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12414J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *1345.59 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with

subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
**Prescribing the 80 mg presentation:**
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**
Severe Crohn disease
Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12419P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12372E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9078T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12361N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised

adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9104E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12363Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5283C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12399N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 5284D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12425Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12360M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12393G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was

ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
**Prescribing the 80 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
**Requests for quantities/repeats insufficient to complete 16 weeks:**
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg

per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12426B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12409D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an

alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.
Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10960W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12391E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior

conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10961X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12358K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (recommencement of treatment)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12356H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12454L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12337H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 706.70 | 30.00 | [a] Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12357J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *864.91 | 30.00 | [a] Amgevita [XT] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for

infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9102C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12375H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that

they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 9034L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 12398M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the

alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8964T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12405X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

8966X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12446C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
**Prescribing the 80 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
**Requests for quantities/repeats insufficient to complete 16 weeks:**
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10413C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12388B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12373F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12432H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
**Prescribing the 80 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
**Requests for quantities/repeats insufficient to complete 16 weeks:**
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10419J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12416L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12338J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12455M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be

assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9100Y | 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12390D | 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD

treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8741C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12430F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate

biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
**Prescribing the 80 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12374G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12339K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab,

secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9428F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12377K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant

continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted

within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9427E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12422T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.
From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.
Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.
Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the

third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats**.**
**Prescribing the 80 mg presentation:**
For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
**Requests for quantities/repeats insufficient to complete 16 weeks:**
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**

- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12407B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 706.70 | 30.00 | [a] Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12332C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *864.91 | 30.00 | [a] Amgevita [XT] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have

completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.
**Prescribing the 40 mg presentation:**
One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
**Prescribing the 80 mg presentation:**
One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12386X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

8965W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12340L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12381P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological

medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be at least 18 years of age.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12402R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9190Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12345R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12433J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5281Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12364R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than

5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater

than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index

(PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12447D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 676.79 | 30.00 | Humira [VE] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12394H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 676.79 | 30.00 | Humira [VE] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is

not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

5282B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12428D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at

any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12331B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8963R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12380N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12397L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one

time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be at least 18 years of age.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12387Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9188N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12451H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12453K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9103D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12376J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 9077R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 12442W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug

within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a

parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9101B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12362P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy

(Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Services Australia
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HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9033K | 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |

| | | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |
|---|---|---|---|---|---|---|---|

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12378L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline

measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8737W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12400P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab

bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 9099X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 827.02 | 30.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12429E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same

PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10944B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12333D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12359L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12382Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.
Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10955N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12370C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2448.09 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12347W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | .. | .. | *2014.38 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12412G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.
From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients

40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.
For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12371D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 706.70 | 30.00 | [a] Humira [VE] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12350B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *864.91 | 30.00 | [a] Amgevita [XT] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab,

secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5

years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling

are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9426D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 4 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12342N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 4 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**
Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9425C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 4 | .. | 827.02 | 30.00 | [a] Amgevita [XT]<br>[a] Hyrimoz [SZ] | [a] Hadlima [RF]<br>[a] Idacio [PK] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12421R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 4 | .. | 676.79 | 30.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ▪ CERTOLIZUMAB PEGOL

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11321W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10892G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

**AND**

- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11318Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10897M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11320T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10137M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time)

providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

**AND**

- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11326D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10896L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11325C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

3425G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

12028C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

12005W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an

alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

**AND**

- The treatment must provide no more than the balance of up to 20 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

12013G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

12040Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat

prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs

specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11322X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10905Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to

Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11324B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10238W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1026.68 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing

spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11319R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10904X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

12027B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

12063X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

## ▪ CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11323Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10909E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3018.54 | 30.00 | Cimzia [UC] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required (STREAMLINED)**

***9156***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11202N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11216H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops

providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required (STREAMLINED)**

***7276***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11218K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11211C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***9481***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11215G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11217J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3448L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a

treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

3450N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

3449M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab,

etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required (STREAMLINED)**

***8887***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

***8955***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11221N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11225T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11197H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to

any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11204Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8638P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment

with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8779C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11201M | 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11196G | 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological

medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11220M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11219L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9456Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9086F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9460X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9090K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was

approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent

continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11207W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3445H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9036N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for

infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11198J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11208X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date

of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

3447K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

3446J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in

PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9458T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9088H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11223Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of

disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9429G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or

have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11222P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11224R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9462B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9431J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same

biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR

- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**

- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8637N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9035M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that

they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9457R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9087G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.
Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii)

leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9459W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9089J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
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HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8778B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing

Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9455P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9085E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the

date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9037P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *845.63 | 30.00 | Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological

medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction

for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9461Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9091L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Brenzys [RF] | [a] Enbrel [PF] |

## ▪ ETANERCEPT

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:
(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(ii) the patient has a current PASI score greater than 15
Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3 ) due to a disease flare with psoriasis affecting the face, hand or foot if:
(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessmentwill be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of thelast administered dose.
To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Therefore, remind the patient to return for clinical review in approximately 12 weeks to enable ample time to obtain the final 8 weeks of treatment of a 24-week treatment course.
Document the patient's baseline disease severity indices scores in their medical record, in addition to stating them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the event that the patient's treating clinician changes, the baseline value(s) are available to the new clinician without need to refer to a third party.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.
Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
Details of the accepted toxicities including severity can be found on the Services Australia website.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:
(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.
A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:
(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
(iii) the PASI score that followed each prior therapy trialled;
(iv) the date the PASI scores were determined
State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Note** Aim to conduct and submit the PASI assessment at week 12 or soon after to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR

- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

State in this authority application, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined

State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Note** Aim to conduct and submit the PASI/percentage of skin area affected assessment at week 12 or soon after to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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## ▪ ETANERCEPT

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3 ) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessmentwill be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of thelast administered dose.

To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have

demonstrated an adequate response to treatment to the initial supply.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.
Therefore, remind the patient to return for clinical review in approximately 12 weeks to enable ample time to obtain the final 8 weeks of treatment of a 24-week treatment course.
Document the patient's baseline disease severity indices scores in their medical record, in addition to stating them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified from week 12; and
(ii) in the event that the patient's treating clinician changes, the baseline value(s) are available to the new clinician without need to refer to a third party.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined

State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**

- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Note** Aim to conduct and submit the PASI assessment at week 12 or soon after to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

State in this authority application, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined

State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Note** Aim to conduct and submit the PASI/percentage of skin area affected assessment at week 12 or soon after to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

1964J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

1963H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 845.62 | 30.00 | [a] Enbrel [PF] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

**golimumab 100 mg/mL injection, 1 mL pen device**

11502J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1123.59 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.
A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.
Treatment cycles:
A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.
Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.
Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment

attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11521J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

11516D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11373N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3432P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response

must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11375Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3428K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11376R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3436W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 100 mg/mL injection, 1 mL pen device**

11381B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1123.59 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**golimumab 100 mg/mL injection, 1 mL pen device**

11382C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | .. | .. | *3295.44 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Clinical criteria:**

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**

- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks duration under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11538G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

11560K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and

submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11365E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3430M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**

- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR

- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11372M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3426H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Services Australia
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Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11361Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3434R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 1161.49 | 30.00 | Simponi [JC] |

## ▪ INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

**infliximab 120 mg/mL injection, 1 mL pen device**

12566J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 383.71 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12555T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 383.71 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

13056E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13078H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

13070X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13058G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR

- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

13061K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13074D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

13075E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13065P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their

first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

**infliximab 120 mg/mL injection, 1 mL pen device**

12584H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12550M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological

medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to

the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

**infliximab 120 mg/mL injection, 1 mL pen device**

12567K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12597B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their

first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 120 mg/mL injection, 1 mL pen device**

12587L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12552P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**infliximab 120 mg/mL injection, 1 mL pen device**

12554R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12553Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**infliximab 120 mg/mL injection, 1 mL pen device**

12560C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12586K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

12551N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12585J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

12575W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12561D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same

biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

12577Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12576X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

**infliximab 120 mg/mL injection, 1 mL pen device**

13054C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13047Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised

treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13048R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13069W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13049T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13057F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a

treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy

of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the condition is affecting the whole body, an adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. State the qualifying PASI score in the authority application.

Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) A reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or

(ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle. State the qualifying numerical percentage figure in the authority application for each affected area.

All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.

**infliximab 120 mg/mL injection, 1 mL pen device**

13076F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13050W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13055D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13072B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in

therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.
A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The most recent fistula assessment must be no more than 1 month old at the time of application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13060J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13073C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus

psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13062L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13067R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

## ▪ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the

new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level

respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13077G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13066Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | .. | *759.43 | 30.00 | Remsima SC [EW] |

*Interleukin inhibitors*

## ▪ GUSELKUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab,

ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**guselkumab 100 mg/mL injection, 1 x 1 mL syringe**

12590P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3796.75 | 30.00 | Tremfya [JC] |

**guselkumab 100 mg/mL injection, 1 x 1 mL pen device**

12568L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3796.75 | 30.00 | Tremfya [JC] |

## ▪ GUSELKUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**guselkumab 100 mg/mL injection, 1 x 1 mL syringe**

11614G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3796.75 | 30.00 | Tremfya [JC] |

## ▪ IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

12209N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3259.13 | 30.00 | Taltz [LY] |

## ▪ IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and

ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.
An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion

of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

11033Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
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HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR

- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:

(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12217B

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## ▪ IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.
Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time)

providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

11623R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 2 | .. | 3259.13 | 30.00 | Taltz [LY] |

## ▪ IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11032P | 1 | 3 | .. | 3259.13 | 30.00 | Taltz [LY] |

## ▪ RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a

minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes**

11827L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: 'Grandfathered' patient - Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions had been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS-subsidised treatment, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022, **AND**
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

**Note** A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: 'Grandfathered' patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where lesions have been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS-subsidised treatment, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022, **AND**
- Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 14 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes**

11858D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 5401.42 | 30.00 | Skyrizi [VE] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to

any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**secukinumab 150 mg/mL injection, 1 mL pen device**

10893H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a

minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10494H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1404.60 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10901R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 1404.60 | 30.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 1 mL pen device**

10898N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 1 mL pen device**

10906B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.
A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.
Treatment cycles:
A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.
Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.
Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.
Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.
A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**secukinumab 150 mg/mL injection, 1 mL pen device**

12297F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**secukinumab 150 mg/mL injection, 1 mL pen device**

12307R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab,

ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10899P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1404.60 | 30.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 1 mL pen device**

10895K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 710.56 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.
(2) Grandfather patients (tofacitinib only).
A patient who commenced treatment with tofacitinib for ankylosing spondylitis prior to 1 August 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.
For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as

initial treatment.
(4) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements will not need to be restated. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### secukinumab 150 mg/mL injection, 1 mL pen device

10890E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *2784.45 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment

attempts.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Treatment phases:
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(2) Continuing treatment.
For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.
Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.
(3) Changing the prescribed biological medicine.
Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.
(6) Balance of Supply
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**

- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 1 mL pen device**

12321L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *3453.52 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10425Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1404.60 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10894J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *5428.41 | 30.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 1 mL pen device**

10900Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *2784.45 | 30.00 | Cosentyx [NV] |

## ▪ SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10910F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tildrakizumab 100 mg/mL injection, 1 mL syringe**

11613F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 3272.18 | 30.00 | Ilumya [RA] |

## ▪ TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who

continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tildrakizumab 100 mg/mL injection, 1 mL syringe**

11616J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3272.18 | 30.00 | Ilumya [RA] |

## ▪ TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any medication with the indication: Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***14150***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11742B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11720W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
Alternative biological medicine refers to adalimumab and etanercept.
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12761P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12762Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.
This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
Alternative biological medicine refers to adalimumab and etanercept.
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021,

**AND**

- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12767Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12768B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any medication with the indication: Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***14104***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be under 30kg, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

13306H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

13301C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Active giant cell arteritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11722Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11721X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Adalimumab and infliximab only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11750K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11730J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Active giant cell arteritis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

**Clinical criteria:**

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; OR
- Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

**Population criteria:**

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include:

(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and

(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11744D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11743C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.
(2) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.
(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.
(4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12094M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12102Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.
Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.
Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been

initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11567T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10954M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** **TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required (STREAMLINED)**

***14088***

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The following reports must be documented in the patient's medical records where appropriate:

(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and

(b) baseline and current pathology reports detailing platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12084B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12099T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed

according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***14084***

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12090H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12086D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12792G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12806B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date

of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11725D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11741Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any medication with the indication: Severe active juvenile idiopathic arthritis.
Treatment cycles:
From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new

treatment cycle.
A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment Phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.
(2) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(3) Changing therapy.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11734N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11748H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(b) details of prior treatment including dose and duration of treatment; and

(c) the pathology reports detailing CRP and platelet count where appropriate.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12083Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12095N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under

these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.
Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
Prescribing under the correct 'Treatment Phase' listing for the authority application.
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.
(2) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.
(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.
Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.
(4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.
(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing.
(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12085C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12105D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different

biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs)

which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11565Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra ACTPen [RO] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10951J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 812.80 | 30.00 | Actemra Subcutaneous Injection [RO] |

## ▪ USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3 ) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or
(ii) 2 of the three subscores are rated severe to very severe; or
(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessmentwill be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of thelast administered dose.
To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

12662K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | .. | .. | 3944.14 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3 ) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessmentwill be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of thelast administered dose.

To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have

demonstrated an adequate response to treatment to the initial supply.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted supply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Whole body) - treatment covering week 28 and onwards

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

12664M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than

5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10767Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 1 | .. | 3944.14 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9305R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 3944.14 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation, **AND**
- The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR

- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;

(ii) the date of commencement of this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ustekinumab 90 mg/mL injection, 1 mL syringe**

13261Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 3971.21 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Selecting the correct treatment phase listing when applying for authority approval:
(1) Initial treatment.
Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.
(2) Continuing treatment.
Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.
(3) Changing therapy.
Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.
(5) Balance of supply.
Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**ustekinumab 90 mg/mL injection, 1 mL syringe**

13273N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 3971.21 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.
However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10774C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 3944.14 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3 ) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessmentwill be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of thelast administered dose.
To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.
Ustekinumab only:
Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.
To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).
A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.
(6B) Re-treatment (etanercept only)
A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.
(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** The 28-weeks of treatment provided by this listing is intended to cover doses occurring at week 0, week 4 and week 16. Based on body weight, request an amount of biological medicine sufficient to cover a dose occurring at these timepoints. The original prescription is intended to cover a dose at week 0 and the 2 repeat prescriptions available are intended to cover doses at week 4 and week 16.
The dose due at week 28 is obtained with the first prescription obtained under the 'Continuing treatment' phase. Remind the patient to return for clinical review at approximately week 24 of treatment to enable ample time to obtain the authority application enabling dosing from week 28 and onwards.
Document the patient's baseline disease severity indices scores in their medical record, in addition to stating them in this authority application, to ensure:
(i) the patient's response to treatment can be quantified; and
(ii) in the event that the patient's treating clinician changes, the baseline value(s) are available to the new clinician without need to refer to a third party.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined

State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 3 doses available under any of the initial treatment phases.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

State in this authority application, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined

State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

12669T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 1 | 2 | .. | 3944.14 | 30.00 | Stelara [JC] |

## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.
From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to

have started their treatment cycle as of 1 September 2017.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).
From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab subcutaneous form only:
Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.
Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.
Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.
(b) Continuing treatment.
Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab patients:
A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.
Vedolizumab patients:
A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.
Adalimumab and infliximab intravenous form only:
Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional

therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that
biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.
(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR

- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

**AND**

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

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| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## ▪ USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4

weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
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HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9304Q | 1 | 2 | .. | 3944.14 | 30.00 | Stelara [JC] |

*Calcineurin inhibitors*

## ▪ CICLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**ciclosporin 100 mg/mL oral liquid, 50 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8661W | 2 | 3 | .. | *721.03 | 30.00 | Neoral [NV] |

**ciclosporin 25 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8658Q | 2 | 3 | .. | *75.05 | 30.00 | [a] APO-Ciclosporin [TX]<br>[a] Neoral 25 [NV] | [a] Cyclosporin Sandoz [SZ] |

**ciclosporin 50 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8659R | 2 | 3 | .. | *143.59 | 30.00 | [a] APO-Ciclosporin [TX]<br>[a] Neoral 50 [NV] | [a] Cyclosporin Sandoz [SZ] |

**ciclosporin 10 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8657P | 2 | 3 | .. | *92.99 | 30.00 | Neoral 10 [NV] |

**ciclosporin 100 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8660T | 2 | 3 | .. | *284.25 | 30.00 | [a] APO-Ciclosporin [TX]<br>[a] Neoral 100 [NV] | [a] Cyclosporin Sandoz [SZ] |

## ▪ TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**tacrolimus 750 microgram capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10870D | 1 | 3 | .. | 174.67 | 30.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 2 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10871E | 1 | 3 | .. | 495.87 | 30.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 3 mg modified release capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11914C | 1 | 2 | .. | 379.53 | 30.00 | ADVAGRAF XL [LQ] |

**tacrolimus 500 microgram capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8646C | 1 | 3 | .. | 115.03 | 30.00 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 0.5 [CR]<br>[a] Tacrograf [RW] |

**tacrolimus 500 microgram modified release capsule, 30**

5299X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 53.33 | 30.00 | ADVAGRAF XL [LQ] |

**tacrolimus 1 mg capsule, 100**

8647D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 222.07 | 30.00 | [a] Pacrolim [AF]<br>[a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] | [a] Pharmacor Tacrolimus 1 [CR]<br>[a] Tacrograf [RW] |

**tacrolimus 1 mg modified release capsule, 60**

5300Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 136.45 | 30.00 | ADVAGRAF XL [LQ] |

**tacrolimus 5 mg capsule, 50**

8648E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 542.92 | 30.00 | [a] Pharmacor Tacrolimus 5 [CR]<br>[a] Tacrograf [RW] | [a] Prograf [LL]<br>[a] Tacrolimus Sandoz [SZ] |

**tacrolimus 5 mg modified release capsule, 30**

5451X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 431.60 | 30.00 | ADVAGRAF XL [LQ] |

*Other immunosuppressants*

## ▪ AZATHIOPRINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**azathioprine 25 mg tablet, 100**

2688L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 23.01 | 24.41 | [a] APO-Azathioprine [TX]<br>[a] NOUMED AZATHIOPRINE [VO] | [a] Azathioprine Sandoz [SZ] |
| | | [B]5.00 | 28.01 | 24.41 | [a] Imuran [AS] | |

**azathioprine 50 mg tablet, 100**

2687K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 30.06 | 30.00 | [a] APO-Azathioprine [TX]<br>[a] Azathioprine GH [GQ]<br>[a] Imazan [ZS]<br>[a] Thioprine 50 [AF] | [a] Azapin [RW]<br>[a] Azathioprine Sandoz [SZ]<br>[a] NOUMED AZATHIOPRINE [VO] |
| | | [B]5.00 | 35.06 | 30.00 | [a] Imuran [AS] | |

## ▪ DIMETHYL FUMARATE

**Authority required (STREAMLINED)**

***10139***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2943X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *399.93 | 30.00 | [a] APO-DIMETHYL FUMARATE [XT]<br>[a] Dimethyl Fumarate Sandoz [SZ]<br>[a] Tecfidera [BD] | [a] Dimethyl Fumarate MSN [LR]<br>[a] Pharmacor Dimethyl Fumarate [CR] |

**dimethyl fumarate 240 mg enteric capsule, 56**

2966D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 735.42 | 30.00 | [a] APO-DIMETHYL FUMARATE [XT]<br>[a] Dimethyl Fumarate Sandoz [SZ]<br>[a] Tecfidera [BD] | [a] Dimethyl Fumarate MSN [LR]<br>[a] Pharmacor Dimethyl Fumarate [CR] |

## ▪ DIMETHYL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10140***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2896K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *399.93 | 30.00 | [a] APO-DIMETHYL FUMARATE [XT]<br>[a] Dimethyl Fumarate Sandoz [SZ]<br>[a] Tecfidera [BD] | [a] Dimethyl Fumarate MSN [LR]<br>[a] Pharmacor Dimethyl Fumarate [CR] |

## ▪ DIROXIMEL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***13072***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

***13034***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**diroximel fumarate 231 mg enteric capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13059H | 1 | 5 | .. | 715.26 | 30.00 | Vumerity [BD] |

## ▪ METHOTREXATE

**methotrexate 10 mg tablet, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2272N | 1 | 3 | .. | 25.09 | 26.49 | Methoblastin [PF] |

**methotrexate 2.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1622J | 1 | 5 | .. | 18.82 | 20.22 | Methoblastin [PF] |

## ▪ METHOTREXATE

**Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1623K | 1 | 2 | .. | 53.31 | 30.00 | Methoblastin [PF] |

## ▪ METHOTREXATE

**Authority required (STREAMLINED)**

***7488***

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**Authority required (STREAMLINED)**

***7518***

Severe psoriasis

**Clinical criteria:**

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11275K | 4 | 5 | .. | *90.41 | 30.00 | Trexject [LM] |

**methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11283W | 4 | 5 | .. | *90.41 | 30.00 | Trexject [LM] |

**methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11268C | 4 | 5 | .. | *90.41 | 30.00 | Trexject [LM] |

**methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11288D | 4 | 5 | .. | *90.41 | 30.00 | Trexject [LM] |

**methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11295L | 4 | 5 | .. | *90.41 | 30.00 | Trexject [LM] |

## ▪ PIRFENIDONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**pirfenidone 801 mg tablet, 90**

11410M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2931.38 | 30.00 | Esbriet [RO] |

## ▪ PIRFENIDONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**pirfenidone 267 mg capsule, 270**

11136D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 2931.38 | 30.00 | Esbriet [RO] |

**pirfenidone 267 mg tablet, 90**

11406H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *2931.42 | 30.00 | Esbriet [RO] |

# ■ MUSCULO-SKELETAL SYSTEM

## ■ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

*Acetic acid derivatives and related substances*

### ▪ DICLOFENAC

**diclofenac sodium 100 mg suppository, 20**

1302M (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *29.41 | 30.00 | Voltaren 100 [NV] |

**diclofenac sodium 100 mg suppository, 20**

5079H (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *29.41 | 30.00 | Voltaren 100 [NV] |

**diclofenac sodium 25 mg enteric tablet, 50**

1299J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 3 | .. | *18.41 | 19.81 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac AN [EA]<br>[a] Fenac 25 [AF] | [a] Clonac 25 [RW]<br>[a] Diclofenac Sandoz [SZ] |
| | | [B]3.40 | *21.81 | 19.81 | [a] Voltaren 25 [NV] | |

**diclofenac sodium 25 mg enteric tablet, 50**

5076E (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *18.41 | 19.81 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac AN [EA]<br>[a] Fenac 25 [AF] | [a] Clonac 25 [RW]<br>[a] Diclofenac Sandoz [SZ] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | [B]3.40 | *21.81 | 19.81 | [a] Voltaren 25 [NV] | |

**diclofenac sodium 50 mg enteric tablet, 50**

| 1300K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | .. | 15.90 | 17.30 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac AN [EA]<br>[a] Fenac [AF] | [a] Clonac 50 [RW]<br>[a] Diclofenac Sandoz [SZ] |
| | | | [B]3.23 | 19.13 | 17.30 | [a] Voltaren 50 [NV] | |

**diclofenac sodium 50 mg enteric tablet, 50**

| 5077F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Diclofenac [TX]<br>[a] Diclofenac AN [EA]<br>[a] Fenac [AF] | [a] Clonac 50 [RW]<br>[a] Diclofenac Sandoz [SZ] |
| | | | [B]3.23 | 19.13 | 17.30 | [a] Voltaren 50 [NV] | |

## ▪ INDOMETACIN

**indometacin 100 mg suppository, 20**

| 2757D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *26.97 | 28.37 | Indocid [AS] |

**indometacin 100 mg suppository, 20**

| 5128X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *26.97 | 28.37 | Indocid [AS] |

## ▪ INDOMETACIN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

| 2454E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | .. | *19.65 | 21.05 | [a] Arthrexin [AF] |
| | | | [B]4.04 | *23.69 | 21.05 | [a] Indocid [AS] |

## ▪ INDOMETACIN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

| 5126T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | .. | .. | *19.65 | 21.05 | [a] Arthrexin [AF] |
| | | | [B]4.04 | *23.69 | 21.05 | [a] Indocid [AS] |

*Oxicams*

## ▪ MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**meloxicam 7.5 mg capsule, 30**

8887R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 16.50 | 17.90 | [a] APO-Meloxicam [TX]<br>[a] MELOBIC [RF]<br>[a] Movalis 7.5 [RW]<br>[a] Terry White Chemists Meloxicam [TW] | [a] Chem mart Meloxicam [CH]<br>[a] Meloxicam Sandoz [SZ]<br>[a] Moxicam [AF] |
| | | [B]2.82 | 19.32 | 17.90 | [a] Mobic [BY] | |

**meloxicam 7.5 mg tablet, 30**

8561N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 16.50 | 17.90 | [a] APX-Meloxicam [TY]<br>[a] MELOBIC [RF]<br>[a] Meloxicam Sandoz [SZ]<br>[a] Moxicam 7.5 [AF] | [a] CIPLA MELOXICAM 7.5 [LR]<br>[a] Meloxibell [GQ]<br>[a] Movalis 7.5 [RW]<br>[a] Pharmacor Meloxicam 7.5 [CR] |
| | | [B]2.82 | 19.32 | 17.90 | [a] Mobic [BY] | |

## ▪ MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**meloxicam 15 mg tablet, 30**

8562P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.20 | 18.60 | [a] APX-Meloxicam [TY]<br>[a] MELOBIC [RF]<br>[a] Meloxicam Sandoz [SZ]<br>[a] Movalis 15 [RW]<br>[a] Pharmacor Meloxicam 15 [CR] | [a] CIPLA MELOXICAM 15 [LR]<br>[a] Meloxibell [GQ]<br>[a] Meloxicam Viatris [AL]<br>[a] Moxicam 15 [AF] |
| | | [B]2.88 | 20.08 | 18.60 | [a] Mobic [BY] | |

**meloxicam 15 mg capsule, 30**

8888T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.20 | 18.60 | [a] APO-Meloxicam [TX]<br>[a] MELOBIC [RF]<br>[a] Movalis 15 [RW]<br>[a] Terry White Chemists Meloxicam [TW] | [a] Chem mart Meloxicam [CH]<br>[a] Meloxicam Sandoz [SZ]<br>[a] Moxicam [AF] |
| | | [B]2.88 | 20.08 | 18.60 | [a] Mobic [BY] | |

## ▪ PIROXICAM

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**piroxicam 10 mg capsule, 50**

1897W (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 17.55 | 18.95 | APO-Piroxicam [TX] |

**piroxicam 10 mg capsule, 50**

5203W (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 17.55 | 18.95 | APO-Piroxicam [TX] |

**piroxicam 20 mg capsule, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1898X NP | 1 | 3 | .. | 16.36 | 17.76 | APO-Piroxicam [TX] |

**piroxicam 20 mg capsule, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5204X DP | 1 | .. | .. | 16.36 | 17.76 | APO-Piroxicam [TX] |

**piroxicam 20 mg dispersible tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1896T NP | 1 | 3 | .. | 17.35 | 18.75 | Feldene-D [PF] |

**piroxicam 20 mg dispersible tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5202T DP | 1 | .. | .. | 17.35 | 18.75 | Feldene-D [PF] |

*Propionic acid derivatives*

## ▪ IBUPROFEN

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3192B NP MW | 1 | .. | .. | 15.68 | 17.08 | [a] APO-Ibuprofen 400 [TX] |
| | | | [B]2.51 | 18.19 | 17.08 | [a] Brufen [GO] |

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5124Q DP | 1 | .. | .. | 15.68 | 17.08 | [a] APO-Ibuprofen 400 [TX] |
| | | | [B]2.51 | 18.19 | 17.08 | [a] Brufen [GO] |

## ▪ IBUPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3190X NP | 3 | 3 | .. | *21.06 | 22.46 | [a] APO-Ibuprofen 400 [TX] |
| | | | [B]7.53 | *28.59 | 22.46 | [a] Brufen [GO] |

## ▪ IBUPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5123P DP | 3 | .. | .. | *21.06 | 22.46 | [a] APO-Ibuprofen 400 [TX] |
| | | | [B]7.53 | *28.59 | 22.46 | [a] Brufen [GO] |

## ▪ KETOPROFEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**ketoprofen 200 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1590Q NP | 1 | 3 | .. | 20.55 | 21.95 | [a] Oruvail SR [AV] |
| | | | [B]2.88 | 23.43 | 21.95 | [a] Orudis SR 200 [SW] |

**ketoprofen 200 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5136H DP | 1 | .. | .. | 20.55 | 21.95 | [a] Oruvail SR [AV] |
| | | | [B]2.88 | 23.43 | 21.95 | [a] Orudis SR 200 [SW] |

## ▪ NAPROXEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1615B NP | 1 | 3 | .. | 18.81 | 20.21 | [a] Proxen SR 1000 [IY] |
| | | | [B]0.99 | 19.80 | 20.21 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1674D NP | 2 | 3 | .. | *21.41 | 22.81 | Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1614Y NP | 1 | 3 | .. | 17.46 | 18.86 | [a] Proxen SR 750 [IY] |
| | | | [B]0.87 | 18.33 | 18.86 | [a] Naprosyn SR750 [IX] |

## ▪ NAPROXEN

**Authority required (STREAMLINED)**

***4159***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority required (STREAMLINED)**

***4124***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1658G NP | ‡1 | 3 | .. | 123.68 | 30.00 | Phebra Naproxen Suspension [FF] |

## ▪ NAPROXEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5179N DP | 1 | .. | .. | 18.81 | 20.21 | [a] Proxen SR 1000 [IY] |
| | | | [B]0.99 | 19.80 | 20.21 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5176K DP | 2 | .. | .. | *21.41 | 22.81 | Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5178M | 1 | .. | .. | 17.46 | 18.86 | [a] Proxen SR 750 [IY] |

| | | | | | |
|---|---|---|---|---|---|
| [B]0.87 | 18.33 | 18.86 | [a] Naprosyn SR750 [IX] | | |

## ▪ NAPROXEN

DP

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

1795L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 17.95 | 19.35 | [a] Crysanal [IY] |
| | | [B]1.61 | 19.56 | 19.35 | [a] Anaprox 550 [IX] |

NP

## ▪ NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

5186Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 17.95 | 19.35 | [a] Crysanal [IY] |
| | | [B]1.61 | 19.56 | 19.35 | [a] Anaprox 550 [IX] |

DP

*Fenamates*

## ▪ MEFENAMIC ACID

**Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

**mefenamic acid 250 mg capsule, 50**

1824B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 19.22 | 20.62 | [a] FEMIN [LI] |
| | | [B]2.07 | 21.29 | 20.62 | [a] Ponstan [PF] |

NP

*Coxibs*

## ▪ CELECOXIB

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**celecoxib 100 mg capsule, 60**

8439E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.40 | 18.80 | [a] APX-Celecoxib [TW] | [a] Blooms the Chemist Celecoxib [IB] |
| | | | | | [a] Celaxib [AF] | [a] Celebrex [UJ] |
| | | | | | [a] Celecoxib APOTEX [TY] | [a] Celecoxib GH [GQ] |
| | | | | | [a] Celecoxib Sandoz [SZ] | [a] Celexi [RW] |
| | | | | | [a] NOUMED CELECOXIB [VO] | |

NP

**celecoxib 200 mg capsule, 30**

8440F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.40 | 18.80 | [a] APX-Celecoxib [TW] | [a] Blooms the Chemist Celecoxib [IB] |
| | | | | | [a] Celaxib [AF] | [a] Celebrex [UJ] |
| | | | | | [a] Celecoxib APOTEX [TY] | [a] Celecoxib GH [GQ] |
| | | | | | [a] Celecoxib Sandoz [SZ] | [a] Celexi [RW] |
| | | | | | [a] NOUMED CELECOXIB [VO] | |

## SPECIFIC ANTIRHEUMATIC AGENTS

### *Quinolines*

### ▪ HYDROXYCHLOROQUINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**hydroxychloroquine sulfate 200 mg tablet, 100**

1512N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 27.05 | 28.45 | [a] APO- Hydroxychloroquine [TX] | [a] Hequinel [RW] |
| | | | | | [a] Hydroxychloroquine GH [GQ] | [a] Plaquenil [SW] |

### *Gold preparations*

### ▪ AURANOFIN

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**auranofin 3 mg capsule, 60**

2022K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 904.84 | 30.00 | Ridaura [BZ] |

**auranofin 3 mg tablet, 60**

1095P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 165.33 | 30.00 | Ridaura [GH] |

### *Penicillamine and similar agents*

### ▪ PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**penicillamine 125 mg tablet, 100**

2721F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 63.94 | 30.00 | D-Penamine [AL] |

**penicillamine 250 mg tablet, 100**

2838J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 77.00 | 30.00 | D-Penamine [AL] |

### ▪ PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**penicillamine 125 mg tablet, 100**

13458H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *114.99 | 30.00 | D-Penamine [AL] |

**penicillamine 250 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13425N NP | 2 | 1 | .. | *142.41 | 30.00 | D-Penamine [AL] |

# MUSCLE RELAXANTS

## MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

### BACLOFEN

**baclofen 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2729P NP | 1 | 5 | .. | 22.97 | 24.37 | [a] APO-Baclofen [TX]<br>[a] Lioresal 10 [NV] | [a] Clofen 10 [AF]<br>[a] Stelax 10 [RW] |

**baclofen 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2730Q NP | 1 | 5 | .. | 34.80 | 30.00 | [a] APO-Baclofen [TX]<br>[a] Lioresal 25 [NV] | [a] Clofen 25 [AF]<br>[a] Stelax 25 [RW] |

### BACLOFEN

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**baclofen 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13522Q NP | 2 | 5 | .. | *32.95 | 30.00 | [a] APO-Baclofen [TX]<br>[a] Lioresal 10 [NV] | [a] Clofen 10 [AF]<br>[a] Stelax 10 [RW] |

**baclofen 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13359D NP | 2 | 5 | .. | *56.61 | 30.00 | [a] APO-Baclofen [TX]<br>[a] Lioresal 25 [NV] | [a] Clofen 25 [AF]<br>[a] Stelax 25 [RW] |

## MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

*Dantrolene and derivatives*

### DANTROLENE

**Restricted benefit**

Chronic spasticity

**dantrolene sodium hemiheptahydrate 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1779P NP | 1 | 2 | .. | 162.34 | 30.00 | Dantrium [PF] |

# ANTIGOUT PREPARATIONS

## ANTIGOUT PREPARATIONS

*Preparations inhibiting uric acid production*

### ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**allopurinol 100 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2600W NP | 1 | 2 | .. | 17.85 | 19.25 | [a] Allopurinol APOTEX [GX]<br>[a] Allosig [RF]<br>[a] Progout 100 [AF] | [a] Allopurinol Sandoz [SZ]<br>[a] NOUMED ALLOPURINOL [VO] |
| | | | [B]5.62 | 23.47 | 19.25 | [a] Zyloprim [RW] | |

**allopurinol 300 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2604C NP | 1 | 2 | .. | 16.75 | 18.15 | [a] Allopurinol APOTEX [GX]<br>[a] Allosig [RF]<br>[a] Progout 300 [AF] | [a] Allopurinol Sandoz [SZ]<br>[a] NOUMED ALLOPURINOL [VO] |
| | | | [B]5.64 | 22.39 | 18.15 | [a] Zyloprim [RW] | |

## ▪ ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**allopurinol 100 mg tablet, 200**

| 13358C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *22.71 | 24.11 | [a] Allopurinol APOTEX [GX]<br>[a] Allosig [RF]<br>[a] Progout 100 [AF] | [a] Allopurinol Sandoz [SZ]<br>[a] NOUMED ALLOPURINOL [VO] |
| | | | [B]11.24 | *33.95 | 24.11 | [a] Zyloprim [RW] | |

**allopurinol 300 mg tablet, 60**

| 13575L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | .. | *20.51 | 21.91 | [a] Allopurinol APOTEX [GX]<br>[a] Allosig [RF]<br>[a] Progout 300 [AF] | [a] Allopurinol Sandoz [SZ]<br>[a] NOUMED ALLOPURINOL [VO] |
| | | | [B]11.28 | *31.79 | 21.91 | [a] Zyloprim [RW] | |

## ▪ FEBUXOSTAT

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***8921***

Chronic gout

**Clinical criteria:**

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

| 10445R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 50.85 | 30.00 | Adenuric [FK] |

## ▪ FEBUXOSTAT

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***14313***

Chronic gout

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

| 13519M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *88.71 | 30.00 | Adenuric [FK] |

*Preparations increasing uric acid excretion*

## ▪ PROBENECID

**probenecid 500 mg tablet, 100**

| 1940D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 75.35 | 30.00 | Pro-Cid [FF] |

*Preparations with no effect on uric acid metabolism*

## ▪ COLCHICINE

**colchicine 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3410L NP | 1 | 5 | .. | 16.68 | 18.08 | [a] Colcine [CR] | [a] Lengout [LN] |
| | | | [B]2.02 | 18.70 | 18.08 | [a] Colgout [AS] | |

# ▪ DRUGS FOR TREATMENT OF BONE DISEASES

## DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

## ▪ ALENDRONATE

**Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

---

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**alendronate 70 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8511Y NP | 1 | 5 | .. | 16.90 | 18.30 | [a] Alendronate Sandoz [SZ]<br>[a] Fonat [AL] | [a] APO-Alendronate [TX] |

## ▪ ALENDRONATE

**Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**alendronate 70 mg tablet, 4**

13499L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *20.81 | 22.21 | [a] Alendronate Sandoz [SZ]<br>[a] Fonat [AL] | [a] APO-Alendronate [TX] |

## ▪ IBANDRONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**ibandronate 50 mg tablet, 28**

9357L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 218.91 | 30.00 | Bondronat [IX] |

## ▪ PAMIDRONATE DISODIUM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Symptomatic Paget disease of bone

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

8461H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | .. | .. | *72.41 | 30.00 | Pamisol [PF] |

**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

8462J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *72.41 | 30.00 | Pamisol [PF] |

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

8463K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 72.41 | 30.00 | Pamisol [PF] |

## ▪ RISEDRONATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Symptomatic Paget disease of bone

### risedronate sodium 30 mg tablet, 28

8482K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 180.19 | 30.00 | Actonel [TT] |

## ▪ RISEDRONATE

**Restricted benefit**
Corticosteroid-induced osteoporosis
**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**
Osteoporosis
**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**
Established osteoporosis
**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### risedronate sodium 35 mg enteric tablet, 4

8972F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 30.00 | Actonel EC [TT] |

### risedronate sodium 5 mg tablet, 28

8481J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 30.00 | Actonel [TT] |

### risedronate sodium 150 mg tablet, 1

9391G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 39.02 | 30.00 | [a] Actonel Once-a-Month [TT] | [a] APO-Risedronate [TX] |

### risedronate sodium 35 mg tablet, 4

8621R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 30.00 | [a] APO-Risedronate [TX] | [a] Risedronate Sandoz [SZ] |

## ▪ RISEDRONATE

**Restricted benefit**
Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**risedronate sodium 35 mg enteric tablet, 4**

13364J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *61.01 | 30.00 | Actonel EC [TT] |

**risedronate sodium 5 mg tablet, 28**

13360E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *61.01 | 30.00 | Actonel [TT] |

**risedronate sodium 150 mg tablet, 1**

13488X (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *65.05 | 30.00 | [a] Actonel Once-a-Month [TT] | [a] APO-Risedronate [TX] |

**risedronate sodium 35 mg tablet, 4**

13459J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *61.01 | 30.00 | [a] APO-Risedronate [TX] | [a] Risedronate Sandoz [SZ] |

## ▪ ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

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**Authority required (STREAMLINED)**

***5710***

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9350D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 85.31 | 30.00 | [a] Aclasta [HX]<br>[a] Zoledasta [TX] | [a] Osteovan [SZ]<br>[a] Zoledronate-RDY 5 [RI] |

[a] Zoledronic Acid SUN [RA]

## ▪ ZOLEDRONIC ACID

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6308***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6313***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6318***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9288W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 85.31 | 30.00 | [a] Aclasta [HX] | [a] Osteovan [SZ] |
| | | | | | [a] Zoledasta [TX] | [a] Zoledronate-RDY 5 [RI] |
| | | | | | [a] Zoledronic Acid SUN [RA] | |

*Bisphosphonates, combinations*

## ▪ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4**

9183H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.53 | 19.93 | [a] ALENDRONATE PLUS D3 70mg/140ug APOTEX [GX] | [a] Alendronate Plus D3 Sandoz [SZ] |
| | | [B]3.20 | 21.73 | 19.93 | [a] Fosamax Plus 70 mg/140 mcg [MQ] | |

## ▪ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)**

***6307***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6320***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6315***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4**

9012H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.53 | 19.93 | [a] ALENDRONATE PLUS D3 70mg/70ug APOTEX [GX] | [a] Alendronate Plus D3 Sandoz [SZ] |
| | | [B]3.20 | 21.73 | 19.93 | [a] Fosamax Plus [MQ] | |

*Other drugs affecting bone structure and mineralization*

## ▪ CALCITRIOL

**Authority required (STREAMLINED)**

***5401***

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

***5255***

Hypoparathyroidism

**Authority required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

***5402***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

2502Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 29.11 | 30.00 | [a] APO-Calcitriol [TX] | [a] Calciprox [ZS] |
| | | | | | [a] Calcitriol AN [EA] | [a] CALITROL [ED] |
| | | | | | [a] Kosteo [RW] | [a] Sical [AF] |
| | | [B]2.29 | 31.40 | 30.00 | [a] Rocaltrol [IX] | |

## ▪ CALCITRIOL

**Authority required (STREAMLINED)**

***14322***

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

***14287***

Hypoparathyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)**

***14231***

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)**

***14296***

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)**

***14259***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

13457G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 3 | .. | *45.23 | 30.00 | [a] APO-Calcitriol [TX] | [a] Calciprox [ZS] |
| | | | | | [a] Calcitriol AN [EA] | [a] CALITROL [ED] |
| | | | | | [a] Kosteo [RW] | [a] Sical [AF] |
| | | [B]4.58 | *49.81 | 30.00 | [a] Rocaltrol [IX] | |

## ▪ DENOSUMAB

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4504***

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

10061M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 461.66 | 30.00 | Xgeva [AN] |

## ▪ DENOSUMAB

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4158***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)**

***4150***

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

5110Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 461.66 | 30.00 | Xgeva [AN] |

## ▪ DENOSUMAB

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6548***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***6524***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**denosumab 60 mg/mL injection, 1 mL syringe**

5457F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 251.50 | 30.00 | Prolia [AN] |

## ▪ RALOXIFENE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***6314***

Established post-menopausal osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**raloxifene hydrochloride 60 mg tablet, 28**

8363E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.83 | 30.00 | [a] APO-Raloxifene [TX] | [a] Fixta 60 [ZS] |
| | | | | | [a] RALOVISTA [RF] | [a] Raloxifene GH [GQ] |
| | | [B]4.09 | 33.92 | 30.00 | [a] Evista [LY] | |

## ▪ RALOXIFENE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

***14274***

Established post-menopausal osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**raloxifene hydrochloride 60 mg tablet, 28**

13426P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *46.67 | 30.00 | [a] APO-Raloxifene [TX] | [a] Fixta 60 [ZS] |
| | | | | | [a] RALOVISTA [RF] | [a] Raloxifene GH [GQ] |
| | | [B]8.18 | *54.85 | 30.00 | [a] Evista [LY] | |

## ▪ ROMOSOZUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**

- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised teriparatide; OR
- Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes**

12301K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 405.66 | 30.00 | Evenity [AN] |

## ▪ TERIPARATIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***12492***

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum

requirement of 12 months continuous therapy**.** Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority required (STREAMLINED)**

***12270***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

12670W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 176.83 | 30.00 | Terrosa [FX] |

## ▪ VOSORITIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Achondroplasia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for FGFR3 gene mutation.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**Authority required**

Achondroplasia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS subsidised vosoritide treatment for this condition, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR

- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**Authority required**

Achondroplasia

Treatment Phase: Grandfather treatment (transition from non-PBS subsidised treatment)

**Clinical criteria:**

- Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing, **AND**
- Patient must have received non-PBS subsidised vosoritide treatment for this condition prior to 1 May 2023, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for FGFR3 gene mutation.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**vosoritide 400 microgram injection [10 vials] (&) inert substance diluent [10 x 0.5 mL syringes], 1 pack**

13275Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *27840.15 | 30.00 | Voxzogo [IO] |

**vosoritide 560 microgram injection [10 vials] (&) inert substance diluent [10 x 0.7 mL syringes], 1 pack**

13274P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *27840.15 | 30.00 | Voxzogo [IO] |

**vosoritide 1.2 mg injection [10 vials] (&) inert substance diluent [10 x 0.6 mL syringes], 1 pack**

13270K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *27840.15 | 30.00 | Voxzogo [IO] |

# ▪ NERVOUS SYSTEM

## ▪ ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

### ▪ CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

12054K DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 0.5 | .. | .. | *22.38 | 23.78 | Aspen Pharma Pty Ltd [AS] |

## ▪ CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

5063L DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 22.54 | 23.94 | Aspen Pharma Pty Ltd [AS] |

## ▪ CODEINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

12065B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 0.5 | .. | .. | *22.38 | 23.78 | Aspen Pharma Pty Ltd [AS] |

## ▪ CODEINE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**codeine phosphate hemihydrate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1214X NP | 1 | .. | .. | 22.54 | 23.94 | Aspen Pharma Pty Ltd [AS] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12045Y DP | 0.5 | .. | .. | *23.75 | 25.15 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12032G DP | 0.5 | .. | .. | *25.16 | 26.56 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12010D DP | 0.5 | .. | .. | *30.38 | 30.00 | Dilaudid [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12559B DP | 1 | .. | .. | 350.72 | 30.00 | [a] Hikma [LM] | [a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ] |

**hydromorphone hydrochloride 2 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5115F DP | 1 | .. | .. | 24.76 | 26.16 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5116G DP | 1 | .. | .. | 27.03 | 28.43 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5117H DP | 1 | .. | .. | 35.44 | 30.00 | Dilaudid [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12047C NP | 0.5 | .. | .. | *23.75 | 25.15 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12046B NP | 0.5 | .. | .. | *25.16 | 26.56 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12016K NP | 0.5 | .. | .. | *30.38 | 30.00 | Dilaudid [MF] |

## ▪ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload

or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

8421F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 28.94 | 30.00 | [a] Dilaudid-HP [MF] | [a] Hydromorphone-hameln-HP [HW] |
| | | | | | [a] HYDROMORPHONE JUNO-HP [JU] | [a] MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ] |

**hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

8420E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 26.24 | 27.64 | [a] Dilaudid [MF] | [a] Hydromorphone-hameln [HW] |
| | | | | | [a] HYDROMORPHONE JUNO [JU] | [a] MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ] |

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

12582F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 350.72 | 30.00 | [a] Hikma [LM] | [a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ] |

**hydromorphone hydrochloride 2 mg tablet, 20**

8541M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.76 | 26.16 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

8542N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 27.03 | 28.43 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

8543P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 35.44 | 30.00 | Dilaudid [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

10858L (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25.45 | 26.85 | Morphine Juno [JU] |

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

5169C (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.21 | 25.61 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

5170D (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25.86 | 27.26 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5239R DP | 1 | .. | .. | 35.15 | 30.00 | Ordine 10 [MF] |

**morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5237P DP | 1 | .. | .. | 31.26 | 30.00 | Ordine 2 [MF] |

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5238Q DP | 1 | .. | .. | 32.60 | 30.00 | Ordine 5 [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10863R DP | 1 | .. | .. | 22.92 | 24.32 | [a] Morphine Juno [JU] |

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5168B DP | 1 | .. | .. | 23.13 | 24.53 | [a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

10874H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25.45 | 26.85 | Morphine Juno [JU] |

**morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

10869C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 30.30 | 30.00 | Morphine Juno [JU] |

**morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules**

10878M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 38.38 | 30.00 | Morphine Juno [JU] |

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

1645N (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.21 | 25.61 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

1647Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25.86 | 27.26 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

2124T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 35.15 | 30.00 | Ordine 10 [MF] |

NP

**morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

2122Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 31.26 | 30.00 | Ordine 2 [MF] |

NP

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

2123R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 32.60 | 30.00 | Ordine 5 [MF] |

NP

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have cancer pain, **AND**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Cancer pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 10 mg tablet, 20**

8669G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 22.69 | 24.09 | Sevredol [MF] |

**morphine sulfate pentahydrate 20 mg tablet, 20**

8670H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 23.44 | 24.84 | Sevredol [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| 10864T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | .. | .. | 22.92 | 24.32 | [a] Morphine Juno [JU] |

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| 1644M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | .. | .. | 23.13 | 24.53 | [a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets**

12053J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 124.12 | 30.00 | MS Contin Suspension 200 mg [MF] |

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

12055L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 120.77 | 30.00 | MS Contin [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 10 mg modified release capsule, 28**

8349K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 27.65 | 29.05 | Kapanol [YN] |

**morphine sulfate pentahydrate 100 mg modified release capsule, 28**

2841M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 60.09 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 120 mg modified release capsule, 14**

8494C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 48.87 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 20 mg modified release capsule, 28**

2839K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 28.55 | 29.95 | Kapanol [YN] |

**morphine sulfate pentahydrate 30 mg modified release capsule, 14**

8491X (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 28.03 | 29.43 | MS Mono [MF] |

**morphine sulfate pentahydrate 50 mg modified release capsule, 28**

2840L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 40.51 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 60 mg modified release capsule, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8492Y NP | 1 | .. | .. | 35.64 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 90 mg modified release capsule, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8493B NP | 1 | .. | .. | 39.29 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8306E NP | 1 | .. | .. | 70.96 | 30.00 | MS Contin Suspension 100 mg [MF] |

**morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8490W NP | 1 | .. | .. | 53.14 | 30.00 | MS Contin Suspension 20 mg [MF] |

**morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8146R NP | 1 | .. | .. | 54.35 | 30.00 | MS Contin Suspension 30 mg [MF] |

**morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8305D NP | 1 | .. | .. | 59.68 | 30.00 | MS Contin Suspension 60 mg [MF] |

**morphine sulfate pentahydrate 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1653B NP | 1 | .. | .. | 25.31 | 26.71 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1656E NP | 1 | .. | .. | 61.49 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8489T NP | 1 | .. | .. | 31.30 | 30.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1654C NP | 1 | .. | .. | 35.66 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8035X NP | 1 | .. | .. | 24.94 | 26.34 | MS Contin [MF] |

**morphine sulfate pentahydrate 60 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1655D NP | 1 | .. | .. | 48.88 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**

- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets**

8454Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 124.12 | 30.00 | MS Contin Suspension 200 mg [MF] |

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

8453X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 120.77 | 30.00 | MS Contin [MF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg capsule, 10**

12311Y DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 21.08 | 22.48 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg tablet, 10**

13234M DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 19.83 | 21.23 | [a] Oxycodone Viatris [MQ] |
| | | [B]1.00 | 20.83 | 21.23 | [a] ENDONE [AF] |

**oxycodone hydrochloride 10 mg capsule, 20**

12074L DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 0.5 | .. | .. | *22.58 | 23.98 | OxyNorm [MF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

5197M DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 22.86 | 24.26 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg capsule, 20**

5191F DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 23.58 | 24.98 | OxyNorm [MF] |

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

5190E DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 31.41 | 30.00 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

5195K DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 21.08 | 22.48 | [a] Mayne Pharma Oxycodone IR [YN] | [a] Oxycodone Mylan [AL] |
| | | | | | [a] Oxycodone Viatris [MQ] | [a] Oxyndone [TX] |
| | | [B]2.00 | 23.08 | 22.48 | [a] ENDONE [AF] | |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone 30 mg suppository, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5194J DP | 1 | .. | .. | 50.52 | 30.00 | Proladone [FF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg capsule, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12314D NP | 1 | .. | .. | 21.08 | 22.48 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13233L NP | 1 | .. | .. | 19.83 | 21.23 | [a] Oxycodone Viatris [MQ] |
| | | | [B]1.00 | 20.83 | 21.23 | [a] ENDONE [AF] |

**oxycodone hydrochloride 10 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12031F NP | 0.5 | .. | .. | *22.58 | 23.98 | OxyNorm [MF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### oxycodone 30 mg suppository, 12

2481N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 50.52 | 30.00 | Proladone [FF] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8501K NP | 1 | .. | .. | 22.86 | 24.26 | OxyNorm [MF] |

**oxycodone hydrochloride 20 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8502L NP | 1 | .. | .. | 26.21 | 27.61 | OxyNorm [MF] |

**oxycodone hydrochloride 5 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8464L NP | 1 | .. | .. | 23.58 | 24.98 | OxyNorm [MF] |

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8644Y NP | 1 | .. | .. | 31.41 | 30.00 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2622B NP | 1 | .. | .. | 21.08 | 22.48 | [a] Mayne Pharma Oxycodone IR [YN] | [a] Oxycodone Mylan [AL] |
| | | | | | | [a] Oxycodone Viatris [MQ] | [a] Oxyndone [TX] |
| | | | [B]2.00 | 23.08 | 22.48 | [a] ENDONE [AF] | |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR

- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg modified release tablet, 28**

8385H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 29.17 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 15 mg modified release tablet, 28**

9399Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 37.41 | 30.00 | OxyContin [MF] |

**oxycodone hydrochloride 20 mg modified release tablet, 28**

8386J (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 37.65 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 30 mg modified release tablet, 28**

9400R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 50.99 | 30.00 | OxyContin [MF] |

**oxycodone hydrochloride 40 mg modified release tablet, 28**

8387K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 47.63 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 80 mg modified release tablet, 28**

8388L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 66.44 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

## ▪ OXYCODONE + NALOXONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

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**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8934F NP | 1 | .. | .. | 36.90 | 30.00 | Targin 10/5mg [MF] |

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8935G NP | 1 | .. | .. | 51.39 | 30.00 | Targin 20/10mg [MF] |

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8936H NP | 1 | .. | .. | 68.39 | 30.00 | Targin 40/20mg [MF] |

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8000C NP | 1 | .. | .. | 35.77 | 30.00 | Targin 5/2.5mg [MF] |

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10776E NP | 1 | .. | .. | 28.03 | 29.43 | Targin 2.5/1.25 mg [MF] |

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10757E NP | 1 | .. | .. | 41.25 | 30.00 | Targin 15/7.5mg [MF] |

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10758F NP | 1 | .. | .. | 57.54 | 30.00 | Targin 30/15 mg [MF] |

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11102H NP | 1 | .. | .. | 83.79 | 30.00 | Targin 60/30 [MF] |

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11111T NP | 1 | .. | .. | 87.28 | 30.00 | Targin 80/40 [MF] |

*Phenylpiperidine derivatives*

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 12 microgram/hour patch, 5**

5265D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 25.02 | 26.42 | [a] Denpax [AF] |

**fentanyl 12 microgram/hour patch, 5**

5437E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 26.63 | 28.03 | [a] Fenpatch 12 [RW] |

**fentanyl 12 microgram/hour patch, 5**

8878G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 25.02 | 26.42 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 12 [JC] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 25 microgram/hour patch, 5**

5277R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 26.88 | 28.28 | [a] Denpax [AF] |

**fentanyl 25 microgram/hour patch, 5**

5438F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 28.93 | 30.00 | [a] Fenpatch 25 [RW] |

**fentanyl 25 microgram/hour patch, 5**

8891Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 26.88 | 28.28 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 25 [JC] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-

authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 50 microgram/hour patch, 5**

5278T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 34.18 | 30.00 | [a] Denpax [AF] |

**fentanyl 50 microgram/hour patch, 5**

5439G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 37.95 | 30.00 | [a] Fenpatch 50 [RW] |

**fentanyl 50 microgram/hour patch, 5**

8892B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 34.18 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 50 [JC] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note** **Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**

- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 75 microgram/hour patch, 5**

5279W (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 40.10 | 30.00 | [a] Denpax [AF] |

**fentanyl 75 microgram/hour patch, 5**

5440H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 45.28 | 30.00 | [a] Fenpatch 75 [RW] |

**fentanyl 75 microgram/hour patch, 5**

8893C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 40.10 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 75 [JC] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
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Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 100 microgram/hour patch, 5**

5280X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 45.38 | 30.00 | [a] Denpax [AF] |

**fentanyl 100 microgram/hour patch, 5**

5441J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 51.80 | 30.00 | [a] Fenpatch 100 [RW] |

**fentanyl 100 microgram/hour patch, 5**

8894D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 45.38 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 100 [JC] |

*Diphenylpropylamine derivatives*

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10745***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10747***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10751***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

1606M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 53.61 | 30.00 | Physeptone [AS] |

NP

**methadone hydrochloride 10 mg tablet, 20**

1609Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 23.47 | 24.87 | Physeptone [AS] |

NP

*Oripavine derivatives*

## ▪ BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**buprenorphine 10 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8866P NP | 1 | .. | .. | 34.78 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 20 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8867Q NP | 1 | .. | .. | 43.80 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 5 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8865N NP | 1 | .. | .. | 27.40 | 28.80 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 15 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10770W NP | 1 | .. | .. | 39.29 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 25 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10756D NP | 1 | .. | .. | 48.07 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 30 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10755C NP | 1 | .. | .. | 52.34 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 40 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10746N NP | 1 | .. | .. | 60.89 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

*Opioids in combination with non-opioid analgesics*

## ▪ PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12066C DP | 0.5 | .. | .. | *16.29 | 17.69 | [a] APO- Paracetamol/Codeine 500/30 [TX]<br>[a] Codalgin Forte [AF]<br>[a] Comfarol Forte [SZ]<br>[a] Prodeine Forte [AV] | [a] APX-Paracetamol/Codeine [TY]<br>[a] Codapane Forte 500/30 [AL]<br>[a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | | [B]1.80 | *18.09 | 17.69 | [a] Panadeine Forte [SW] | |

## ▪ PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

3316M (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.90 | 17.30 | [a] APO- Paracetamol/Codeine 500/30 [TX]<br>[a] Codalgin Forte [AF]<br>[a] Comfarol Forte [SZ]<br>[a] Prodeine Forte [AV] | [a] APX-Paracetamol/Codeine [TY]<br>[a] Codapane Forte 500/30 [AL]<br>[a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | [B]2.90 | 18.80 | 17.30 | [a] Panadeine Forte [SW] | |

## ▪ PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

12022R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *16.29 | 17.69 | [a] APO- Paracetamol/Codeine 500/30 [TX]<br>[a] Codalgin Forte [AF]<br>[a] Comfarol Forte [SZ]<br>[a] Prodeine Forte [AV] | [a] APX-Paracetamol/Codeine [TY]<br>[a] Codapane Forte 500/30 [AL]<br>[a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | [B]1.80 | *18.09 | 17.69 | [a] Panadeine Forte [SW] | |

## ▪ PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1215Y NP | 1 | .. | .. | 15.90 | 17.30 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] APX-Paracetamol/Codeine [TY] |
| | | | | | | [a] Codalgin Forte [AF] | [a] Codapane Forte 500/30 [AL] |
| | | | | | | [a] Comfarol Forte [SZ] | [a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | | | | | [a] Prodeine Forte [AV] | |
| | | | [B]2.90 | 18.80 | 17.30 | [a] Panadeine Forte [SW] | |

*Other opioids*

## ▪ TAPENTADOL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tapentadol 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10094G NP | 1 | .. | .. | 36.49 | 30.00 | Palexia SR [CS] |

**tapentadol 150 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10100N NP | 1 | .. | .. | 43.67 | 30.00 | Palexia SR [CS] |

**tapentadol 200 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10091D NP | 1 | .. | .. | 50.02 | 30.00 | Palexia SR [CS] |

**tapentadol 250 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10092E NP | 1 | .. | .. | 55.39 | 30.00 | Palexia SR [CS] |

**tapentadol 50 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10096J NP | 1 | .. | .. | 29.02 | 30.00 | Palexia SR [CS] |

## ▪ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12024W DP | 0.5 | .. | .. | *16.29 | 17.69 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] Tramedo [AF] | [a] Zydol [RW] |
| | | | [B]1.40 | *17.69 | 17.69 | [a] Tramal [CS] | |

## ▪ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5231H DP | 1 | .. | .. | 16.55 | 17.95 | [a] Tramadol AN [JU] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] Tramal 100 [CS] | |

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5150C DP | ‡1 | .. | .. | 19.33 | 20.73 | Tramal [CS] |

**tramadol hydrochloride 50 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5232J DP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] Tramedo [AF] | [a] Zydol [RW] |
| | | | [B]2.25 | 18.15 | 17.30 | [a] Tramal [CS] | |

## ▪ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

12008B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 0.5 | .. | .. | *16.29 | 17.69 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | [a] Tramedo [AF] | [a] Zydol [RW] |
| | | [B]1.40 | *17.69 | 17.69 | [a] Tramal [CS] | |

## ▪ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8582Q NP | 1 | .. | .. | 16.55 | 17.95 | [a] Tramadol AN [JU]<br>[a] Tramal 100 [CS] | [a] Tramadol Sandoz [SZ] |

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8843K NP | ‡1 | .. | .. | 19.33 | 20.73 | Tramal [CS] |

**tramadol hydrochloride 50 mg capsule, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8455B NP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Tramadol [TX]<br>[a] Tramedo [AF] | [a] Tramadol Sandoz [SZ]<br>[a] Zydol [RW] |
| | | | [B]2.25 | 18.15 | 17.30 | [a] Tramal [CS] | |

## ▪ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tramadol hydrochloride 100 mg modified release tablet, 20**

8523N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.14 | 17.54 | [a] APO-Tramadol SR [TX]<br>[a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 100 [RW] | [a] Tramadol Sandoz SR [SZ]<br>[a] Tramedo SR [AL] |
| | | [B]4.29 | 20.43 | 17.54 | [a] Tramal SR 100 [CS] | |

**tramadol hydrochloride 150 mg modified release tablet, 20**

8524P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.90 | 18.30 | [a] APO-Tramadol SR [TX]<br>[a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 150 [RW] | [a] Tramadol Sandoz SR [SZ]<br>[a] Tramedo SR [AL] |
| | | [B]5.23 | 22.13 | 18.30 | [a] Tramal SR 150 [CS] | |

**tramadol hydrochloride 200 mg modified release tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8525Q NP | 1 | .. | .. | 17.06 | 18.46 | [a] APO-Tramadol SR [TX]<br>[a] Tramadol SR generichealth [GQ]<br>[a] Zydol SR 200 [RW] | [a] Tramadol Sandoz SR [SZ]<br>[a] Tramedo SR [AL] |
| | | | [B]5.95 | 23.01 | 18.46 | [a] Tramal SR 200 [CS] | |

**tramadol hydrochloride 50 mg modified release tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2527B NP | 1 | .. | .. | 16.83 | 18.23 | Tramal SR 50 [CS] |

## OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

### ▪ PARACETAMOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**paracetamol 24 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1747Y NP | ‡1 | 2 | .. | 15.79 | 17.19 | Panamax [SW] |

**paracetamol 48 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1770E NP | ‡1 | 2 | .. | 16.84 | 18.24 | Panamax 240 Elixir [SW] |

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1746X NP | 1 | 1 | .. | 14.66 | 16.06 | [a] APO-Paracetamol [TX]<br>[a] Panamax [SW]<br>[a] Paracetamol Sandoz Pharma [QS]<br>[a] Parapane [AF]<br>[a] Wagner Health Paracetamol [BG] | [a] Febridol [EA]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Paralgin [OW]<br>[a] PHARMACY CARE PARACETAMOL [SI] |

### ▪ PARACETAMOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**paracetamol 24 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3348F DP | ‡1 | .. | .. | 15.79 | 17.19 | Panamax [SW] |

**paracetamol 48 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3349G DP | ‡1 | .. | .. | 16.84 | 18.24 | Panamax 240 Elixir [SW] |

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5196L DP | 1 | .. | .. | 14.66 | 16.06 | [a] APO-Paracetamol [TX]<br>[a] Panamax [SW]<br>[a] Paracetamol Sandoz Pharma [QS]<br>[a] Parapane [AF]<br>[a] Wagner Health Paracetamol [BG] | [a] Febridol [EA]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Paralgin [OW]<br>[a] PHARMACY CARE PARACETAMOL [SI] |

### ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5224Y DP | 3 | .. | .. | *18.00 | 19.40 | [a] APO-Paracetamol [TX]<br>[a] Panamax [SW] | [a] Febridol [EA]<br>[a] Paracetamol (Sandoz) [SZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | | [a] Parapane [AF] | [a] PHARMACY CARE PARACETAMOL [SI] |
| | | | | | | [a] Wagner Health Paracetamol [BG] | |

## ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 500 mg tablet, 100**

| | Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|---|
| 8784H NP | 3 | 4 | .. | *18.00 | 19.40 | [a] APO-Paracetamol [TX] | [a] Febridol [EA] | |
| | | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] | |
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] | |
| | | | | | | [a] Parapane [AF] | [a] PHARMACY CARE PARACETAMOL [SI] | |
| | | | | | | [a] Wagner Health Paracetamol [BG] | | |

## ▪ PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 665 mg modified release tablet, 192**

| | Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10797G NP | 1 | 5 | .. | 20.52 | 21.92 | [a] Osteomol 665 Paracetamol [CR] | |

**paracetamol 665 mg modified release tablet, 96**

| | Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|---|
| 8814X NP | 2 | 5 | .. | *20.51 | 21.91 | [a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX] | [a] CHEMISTS' OWN OSTEO RELIEF PARACETAMOL [RF] | |
| | | | | | | [a] Osteomol 665 Paracetamol [CR] | [a] Parapane OSTEO [AF] | |

*Gabapentinoids*

## ▪ PREGABALIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4172***

Neuropathic pain

**Clinical criteria:**

- The condition must be refractory to treatment with other drugs.

**pregabalin 150 mg capsule, 56**

| | Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|---|
| 2355Y NP | 1 | 5 | .. | 22.88 | 24.28 | [a] APO-Pregabalin [TX] | [a] Blooms The Chemist Pregabalin [IB] | |
| | | | | | | [a] Cipla Pregabalin [LR] | [a] LYPRALIN [RW] | |
| | | | | | | [a] Lyrica [UJ] | [a] Lyzalon [AF] | |
| | | | | | | [a] Neuroccord [CR] | [a] NOUMED PREGABALIN [VO] | |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] | |
| | | | | | | [a] Pregabalin GH [GQ] | [a] Pregabalin Lupin [HQ] | |
| | | | | | | [a] Pregabalin Sandoz [SZ] | | |

**pregabalin 25 mg capsule, 56**

| 2348N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 17.13 | 18.53 | [a] APO-Pregabalin [TX] | [a] Blooms The Chemist Pregabalin [IB] |
| | | | | | | [a] Cipla Pregabalin [LR] | [a] LYPRALIN [RW] |
| | | | | | | [a] Lyrica [UJ] | [a] Lyzalon [AF] |
| | | | | | | [a] Neuroccord [CR] | [a] NOUMED PREGABALIN [VO] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin Lupin [HQ] | [a] Pregabalin Sandoz [SZ] |

**pregabalin 300 mg capsule, 56**

| 2363J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 27.74 | 29.14 | [a] APO-Pregabalin [TX] | [a] Blooms The Chemist Pregabalin [IB] |
| | | | | | | [a] Cipla Pregabalin [LR] | [a] LYPRALIN [RW] |
| | | | | | | [a] Lyrica [UJ] | [a] Lyzalon [AF] |
| | | | | | | [a] Neuroccord [CR] | [a] NOUMED PREGABALIN [VO] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin GH [GQ] | [a] Pregabalin Lupin [HQ] |
| | | | | | | [a] Pregabalin Sandoz [SZ] | |

**pregabalin 75 mg capsule, 56**

| 2335X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 19.43 | 20.83 | [a] APO-Pregabalin [TX] | [a] Blooms The Chemist Pregabalin [IB] |
| | | | | | | [a] Cipla Pregabalin [LR] | [a] LYPRALIN [RW] |
| | | | | | | [a] Lyrica [UJ] | [a] Lyzalon [AF] |
| | | | | | | [a] Neuroccord [CR] | [a] NOUMED PREGABALIN [VO] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin GH [GQ] | [a] Pregabalin Lupin [HQ] |
| | | | | | | [a] Pregabalin Sandoz [SZ] | |

## ANTIMIGRAINE PREPARATIONS

*Selective serotonin (5HT1) agonists*

### ▪ ELETRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**eletriptan 40 mg tablet, 4**

| 5290K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.62 | 28.02 | Relpax [UJ] |

**eletriptan 80 mg tablet, 4**

| 5291L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 26.62 | 28.02 | Relpax [UJ] |

### ▪ NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**naratriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8298R NP | 2 | 5 | [S]1.54 | *25.23 | 25.09 | Naramig [AS] |

## ▪ NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**naratriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9734H NP | 2 | 5 | .. | *25.23 | 26.63 | Naramig [AS] |

## ▪ RIZATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

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**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**rizatriptan 10 mg orally disintegrating tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10551H NP | 2 | 5 | .. | *21.59 | 22.99 | [a] APO-Rizatriptan [TX]<br>[a] Rizatriptan AN ODT [EA]<br>[a] Rizatriptan ODT GH [GQ] | [a] RIXALT [RF]<br>[a] Rizatriptan ODT APOTEX [GX] |

**rizatriptan 10 mg wafer, 2**

9313E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | [B]2.74 | *24.33 | 22.99 | [a] Rizatriptan Wafers-10mg [AF] |
| | | [B]3.92 | *25.51 | 22.99 | [a] Maxalt [AL] |

## ▪ SUMATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**sumatriptan 50 mg tablet, 2**

8144P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *19.23 | 20.63 | [a] APO-Sumatriptan [TX]<br>[a] Sumatran [OW] | [a] Iptam [AL] |
| | | [B]4.18 | *23.41 | 20.63 | [a] Imigran [LN] | |

**sumatriptan 50 mg tablet, 4**

1849H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.23 | 20.63 | [a] APO-Sumatriptan [TX]<br>[a] Pharmacor Sumatriptan 50 [CR]<br>[a] Sumatriptan generichealth [GQ] | [a] Iptam [AL]<br>[a] Sumatran [OW]<br>[a] Sumatriptan Sandoz [SZ] |
| | | [B]4.19 | 23.42 | 20.63 | [a] Imigran [LN] | |

**sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation**

8341B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 24.83 | 26.23 | Imigran [AS] |

**SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

10694W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | [B]4.19 | 23.42 | 20.63 | [a] Imigran FDT [AS] |

## ▪ ZOLMITRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**zolmitriptan 2.5 mg tablet, 2**

8266C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *24.87 | 26.27 | [a] APO-Zolmitriptan [TX] | [a] Zoltrip [RW] |
| | | [B]4.50 | *29.37 | 26.27 | [a] Zomig [AP] | |

*Calcitonin gene-related peptide (CGRP) antagonists*

## ▪ EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14189***

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

**eptinezumab 100 mg/mL injection, 1 mL vial**

13342F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1448.31 | 30.00 | Vyepti [LU] |

## ▪ EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12029***

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

**eptinezumab 100 mg/mL injection, 1 mL vial**

13352R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1448.31 | 30.00 | Vyepti [LU] |

## ▪ FREMANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***12029***

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**

- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12603H | 1 | 5 | .. | 559.92 | 30.00 | [a] Ajovy [TB] |

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13129B | 1 | 5 | .. | 559.92 | 30.00 | [a] Ajovy [TB] |

## ▪ FREMANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***12064***

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12611R | 1 | 2 | .. | 559.92 | 30.00 | [a] Ajovy [TB] |

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13115G | 1 | 2 | .. | 559.92 | 30.00 | [a] Ajovy [TB] |

*Other antimigraine preparations*

## ▪ GALCANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12029***

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

**galcanezumab 120 mg/mL injection, 1 mL pen device**

12469G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 522.56 | 30.00 | Emgality [LY] |

## ▪ GALCANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***12064***

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

**galcanezumab 120 mg/mL injection, 1 mL pen device**

12478R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *1037.13 | 30.00 | Emgality [LY] |

## ▪ PIZOTIFEN

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**pizotifen 500 microgram tablet, 100**

3074T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 24.60 | 26.00 | Sandomigran 0.5 [AE] |

# ▪ ANTIEPILEPTICS

## ANTIEPILEPTICS

*Barbiturates and derivatives*

## ▪ PHENOBARBITAL

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**phenobarbital 200 mg (equivalent to phenobarbital sodium 219 mg)/mL injection, 5 x 1 mL ampoules**

2138M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 36.02 | 30.00 | Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd) [AS] |

**phenobarbital 30 mg tablet, 200**

1850J

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 18.60 | 20.00 | Phenobarb [RW] |

## ▪ PRIMIDONE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**primidone 250 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1939C NP | 1 | 2 | .. | 69.89 | 30.00 | Mysoline [LM] |

*Hydantoin derivatives*

## ▪ PHENYTOIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2692Q NP | ‡1 | 3 | .. | 26.11 | 27.51 | Dilantin [UJ] |

**phenytoin 50 mg chewable tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1249R NP | 1 | 2 | .. | 65.17 | 30.00 | Dilantin Infatabs [UJ] |

**phenytoin sodium 100 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1874P NP | 1 | 2 | .. | 33.31 | 30.00 | Dilantin Sodium [UJ] |

**phenytoin sodium 30 mg capsule, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1873N NP | 1 | 2 | .. | 52.56 | 30.00 | Dilantin Sodium [UJ] |

*Succinimide derivatives*

## ▪ ETHOSUXIMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ethosuximide 250 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11703Y NP | 2 | 2 | .. | *295.85 | 30.00 | Zarontin [IX] |

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1414K NP | ‡1 | 5 | .. | 73.58 | 30.00 | Zarontin [IX] |

*Benzodiazepine derivatives*

## ▪ CLONAZEPAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1807D NP | 1 | .. | .. | 23.56 | 24.96 | Rivotril [PB] |

## ▪ CLONAZEPAM

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1808E NP | 2 | .. | .. | *20.51 | 21.91 | Rivotril [PB] |

**clonazepam 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1806C NP | 2 | 2 | .. | *31.97 | 30.00 | Paxam 2 [AF] |

## ▪ CLONAZEPAM

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note** Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Epilepsy
**Clinical criteria:**
- The condition must be neurologically proven.

**clonazepam 500 microgram tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11559J NP | 4 | 2 | [B]3.68 | *30.25 | 27.97 | [a] Rivotril [PB] |

**clonazepam 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1805B NP | 2 | 2 | .. | *26.53 | 27.93 | [a] Paxam 0.5 [AF] |

## ▪ NITRAZEPAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Myoclonic epilepsy
**Authority required**
Malignant neoplasia (late stage)
**Authority required**
Insomnia
**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**
Insomnia
**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2732T NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Alodorm [AF] | [a] Mogadon [IL] |

*Carboxamide derivatives*

## ▪ CARBAMAZEPINE

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5041H DP | ‡1 | .. | .. | 25.97 | 27.37 | Tegretol Liquid [NV] |

**carbamazepine 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5039F DP | 2 | .. | .. | *23.41 | 24.81 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.66 | *26.07 | 24.81 | [a] Tegretol 100 [NV] |

**carbamazepine 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1724R DP | 2 | .. | .. | *30.41 | 30.00 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.62 | *33.03 | 30.00 | [a] Tegretol 200 [NV] |

**carbamazepine 200 mg modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5038E DP | 1 | .. | .. | 30.77 | 30.00 | Tegretol CR 200 [NV] |

**carbamazepine 400 mg modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5037D DP | 1 | .. | .. | 46.77 | 30.00 | Tegretol CR 400 [NV] |

## ▪ CARBAMAZEPINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2427R NP | ‡1 | 5 | .. | 25.97 | 27.37 | Tegretol Liquid [NV] |

**carbamazepine 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2422L NP | 2 | 2 | .. | *23.41 | 24.81 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.66 | *26.07 | 24.81 | [a] Tegretol 100 [NV] |

**carbamazepine 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1706T NP | 2 | 2 | .. | *30.41 | 30.00 | [a] Carbamazepine Sandoz [SZ] |
| | | | [B]2.62 | *33.03 | 30.00 | [a] Tegretol 200 [NV] |

**carbamazepine 200 mg modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2426Q NP | 1 | 2 | .. | 30.77 | 30.00 | Tegretol CR 200 [NV] |

**carbamazepine 400 mg modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2431Y NP | 1 | 2 | .. | 46.77 | 30.00 | Tegretol CR 400 [NV] |

## ▪ OXCARBAZEPINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5183***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**oxcarbazepine 60 mg/mL oral liquid, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8588B NP | 2 | 5 | .. | *99.43 | 30.00 | Trileptal [NV] |

**oxcarbazepine 150 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8584T NP | 1 | 5 | .. | 56.21 | 30.00 | Trileptal [NV] |

**oxcarbazepine 300 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8585W NP | 1 | 5 | .. | 84.32 | 30.00 | Trileptal [NV] |

**oxcarbazepine 600 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8586X NP | 1 | 5 | .. | 133.13 | 30.00 | Trileptal [NV] |

*Fatty acid derivatives*

## ▪ TIAGABINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4928***
Partial epileptic seizures
**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**tiagabine 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8222R NP | 2 | 5 | .. | *110.77 | 30.00 | Gabitril [TB] |

**tiagabine 15 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8223T NP | 2 | 5 | .. | *155.67 | 30.00 | Gabitril [TB] |

**tiagabine 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8221Q NP | 2 | 5 | .. | *61.87 | 30.00 | Gabitril [TB] |

## ▪ VALPROATE

**Caution** There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2293Q NP | 2 | 2 | .. | *40.95 | 30.00 | Epilim Liquid [SW] |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2295T NP | 2 | 2 | .. | *40.95 | 30.00 | Epilim Syrup [SW] |

**valproate sodium 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2294R NP | 2 | 2 | .. | *35.23 | 30.00 | Epilim [SW] |

**valproate sodium 200 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2289L NP | 2 | 2 | .. | *22.95 | 24.35 | [a] Sodium Valproate Sandoz [SZ]<br>[a] Valproate Winthrop EC 200 [WA] | [a] Valprease 200 [RW]<br>[a] Valpro EC 200 [AF] |
| | | | [B]1.70 | *24.65 | 24.35 | [a] Epilim EC [SW] | |

**valproate sodium 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2290M NP | 2 | 2 | .. | *32.71 | 30.00 | [a] Sodium Valproate Sandoz [SZ]<br>[a] Valproate Winthrop EC 500 [WA] | [a] Valprease 500 [RW]<br>[a] Valpro EC 500 [AF] |
| | | | [B]1.70 | *34.41 | 30.00 | [a] Epilim EC [SW] | |

## ▪ VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4929***
Epileptic seizures
**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**vigabatrin 500 mg powder for oral liquid, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2668K NP | 1 | 5 | .. | 60.74 | 30.00 | Sabril [SW] |

**vigabatrin 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2667J NP | 1 | 5 | .. | 86.75 | 30.00 | Sabril [SW] |

*Other antiepileptics*

## ▪ BRIVARACETAM

**Authority required (STREAMLINED)**
***10210***
Intractable partial epileptic seizures
Treatment Phase: Initial treatment
**Treatment criteria:**
- Must be treated by a neurologist.

**Clinical criteria:**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11339T | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 25 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11328F | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11334M | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 75 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11356Q | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

## ▪ BRIVARACETAM

**Authority required (STREAMLINED)**
***10251***
Intractable partial epileptic seizures
Treatment Phase: Initial treatment
**Treatment criteria:**
- Must be treated by a neurologist.

**Clinical criteria:**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11349H | 1 | 5 | .. | 203.82 | 30.00 | Briviact [UC] |

## ▪ BRIVARACETAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***10208***

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11357R NP | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 25 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11327E NP | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11338R NP | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

**brivaracetam 75 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11350J NP | 1 | 5 | .. | 164.66 | 30.00 | Briviact [UC] |

## ▪ BRIVARACETAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***10330***

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11358T NP | 1 | 5 | .. | 203.82 | 30.00 | Briviact [UC] |

## ▪ CANNABIDIOL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe myoclonic epilepsy in infancy (Dravet syndrome)

**Clinical criteria:**

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

**cannabidiol 100 mg/mL oral liquid, 100 mL**

12467E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1534.84 | 30.00 | Epidyolex [EU] |

## ▪ CANNABIDIOL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Seizures of the Lennox-Gastaut syndrome

**Clinical criteria:**

- Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible), **AND**
- Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures, **AND**
- Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**cannabidiol 100 mg/mL oral liquid, 100 mL**

13277T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 1534.84 | 30.00 | Epidyolex [EU] |

## ▪ GABAPENTIN

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4928***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**gabapentin 100 mg capsule, 100**

8505P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.16 | 18.56 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | [a] Gabapentin APOTEX [TY] | [a] GAPENTIN [RF] |
| | | | | | [a] Neurontin [UJ] | [a] Nupentin 100 [AF] |

**gabapentin 300 mg capsule, 100**

1834M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 24.48 | 25.88 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | [a] Gabapentin APOTEX [TY] | [a] Gabapentin generichealth [HQ] |
| | | | | | [a] Gabapentin Sandoz [SZ] | [a] GAPENTIN [RF] |
| | | | | | [a] Neurontin [UJ] | [a] Nupentin 300 [AF] |

**gabapentin 400 mg capsule, 100**

1835N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 28.66 | 30.00 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | [a] Gabapentin APOTEX [TY] | [a] Gabapentin generichealth [HQ] |
| | | | | | [a] Gabapentin Sandoz [SZ] | [a] GAPENTIN [RF] |
| | | | | | [a] Neurontin [UJ] | [a] Nupentin 400 [AF] |

**gabapentin 600 mg tablet, 100**

8559L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 37.85 | 30.00 | [a] Gabapentin AN [EA] | [a] Gabapentin APOTEX [TY] |
| | | | | | [a] GAPENTIN [RF] | [a] Neurontin [UJ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Pharmacor Gabapentin 600 [CR] | |

**gabapentin 800 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8389M NP | 1 | 5 | .. | 46.14 | 30.00 | [a] Gabapentin APOTEX [TY]<br>[a] Neurontin [UJ] | [a] GAPENTIN [RF]<br>[a] Pharmacor Gabapentin 800 [CR] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***8813***

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9333F NP | 1 | 1 | .. | 25.40 | 26.80 | [a] Lacoress [LR]<br>[a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] |

**lacosamide 100 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9334G NP | 1 | 1 | .. | 37.82 | 30.00 | [a] Lacoress [LR]<br>[a] Vimcosa [CR] | [a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

**lacosamide 150 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9336J NP | 1 | 1 | .. | 50.22 | 30.00 | [a] Lacoress [LR]<br>[a] Vimpat [UC] | [a] Vimcosa [CR] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***8815***

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10293R NP | 4 | 5 | .. | *62.65 | 30.00 | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] | [a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

## ▪ LACOSAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***12225***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Dose titration at the start of therapy, during therapy or to gradually cease treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 100 mg tablet, 14**

12633X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 37.82 | 30.00 | [a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] | [a] Vimcosa [CR] |

**lacosamide 150 mg tablet, 14**

12649R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 50.22 | 30.00 | [a] Vimcosa [CR] | [a] Vimpat [UC] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***8770***

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Authority required (STREAMLINED)**

***8815***

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 100 mg tablet, 56**

9335H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 112.30 | 30.00 | [a] Lacoress [LR]<br>[a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.

**Authority required (STREAMLINED)**

***12092***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician, **AND**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

**lacosamide 10 mg/mL oral liquid, 200 mL**

12628P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | .. | *124.75 | 30.00 | Vimpat [UC] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)**

***8770***

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Authority required (STREAMLINED)**

***8815***

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 150 mg tablet, 56**

9337K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 164.38 | 30.00 | [a] Lacoress [LR]<br>[a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] |

**lacosamide 200 mg tablet, 56**

9338L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 216.50 | 30.00 | [a] Lacoress [LR]<br>[a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] |

**lacosamide 10 mg/mL oral liquid, 200 mL**

11694L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡6 | 5 | .. | *358.29 | 30.00 | Vimpat [UC] |

## ▪ LACOSAMIDE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing**.**

**Authority required (STREAMLINED)**

***12092***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician, **AND**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

**lacosamide 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12634Y NP | 1 | 5 | .. | 112.30 | 30.00 | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] | [a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

**lacosamide 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12627N NP | 1 | 5 | .. | 164.38 | 30.00 | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] | [a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

**lacosamide 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12658F NP | 1 | 5 | .. | 216.50 | 30.00 | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] | [a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12626M NP | 4 | 5 | .. | *62.65 | 30.00 | [a] Lacosam [AF]<br>[a] Lacosamide Lupin [GQ]<br>[a] Vimcosa [CR] | [a] Lacosamide ARX [XT]<br>[a] Lacosamide Sandoz [SZ]<br>[a] Vimpat [UC] |

## ▪ LAMOTRIGINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***11081***

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

**lamotrigine 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2850B NP | 1 | 5 | .. | 25.67 | 27.07 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Logem [AL]<br>[a] Reedos 100 [ZS] | [a] APX-Lamotrigine [TY]<br>[a] Lamotrigine GH [GQ]<br>[a] NOUMED LAMOTRIGINE [VO]<br>[a] Sandoz Lamotrigine [HX] |
| | | | [B]4.45 | 30.12 | 27.07 | [a] Lamictal [AS] | |

**lamotrigine 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2851C NP | 1 | 5 | .. | 34.30 | 30.00 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Logem [AL]<br>[a] Reedos 200 [ZS] | [a] APX-Lamotrigine [TY]<br>[a] Lamotrigine GH [GQ]<br>[a] NOUMED LAMOTRIGINE [VO]<br>[a] Sandoz Lamotrigine [HX] |
| | | | [B]4.45 | 38.75 | 30.00 | [a] Lamictal [AS] | |

**lamotrigine 25 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2848X NP | 1 | 5 | .. | 17.65 | 19.05 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF]<br>[a] Logem [AL]<br>[a] Reedos 25 [ZS] | [a] APX-Lamotrigine [TY]<br>[a] Lamotrigine GH [GQ]<br>[a] NOUMED LAMOTRIGINE [VO]<br>[a] Sandoz Lamotrigine [HX] |
| | | | [B]4.46 | 22.11 | 19.05 | [a] Lamictal [AS] | |

**lamotrigine 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8063J NP | 1 | 5 | .. | 19.31 | 20.71 | Lamictal [AS] |

**lamotrigine 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2849Y NP | 1 | 5 | .. | 20.60 | 22.00 | [a] APO-Lamotrigine [TX]<br>[a] LAMITAN [RF] | [a] APX-Lamotrigine [TY]<br>[a] Lamotrigine GH [GQ] |

| | | | | | |
|---|---|---|---|---|---|
| | | | | [a] Logem [AL] | [a] NOUMED LAMOTRIGINE [VO] |
| | | | | [a] Reedos 50 [ZS] | [a] Sandoz Lamotrigine [HX] |
| | [B]4.45 | 25.05 | 22.00 | [a] Lamictal [AS] | |

## ▪ LEVETIRACETAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***11116***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

### levetiracetam 1 g tablet, 60

8656N NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | | 5 | .. | 39.71 | 30.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kevtam 1000 [AF] | [a] Levactam [ZS] |
| | | | | | | [a] Levecetam 1000 [RZ] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam Mylan [AL] | [a] Levetiracetam SZ [SZ] |
| | | | | | | [a] Levi 1000 [RW] | [a] NOUMED LEVETIRACETAM [VO] |

### levetiracetam 250 mg tablet, 60

8654L NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | | 5 | .. | 22.61 | 24.01 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kevtam 250 [AF] | [a] Levactam [ZS] |
| | | | | | | [a] Levecetam 250 [RZ] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam Mylan [AL] | [a] Levetiracetam SZ [SZ] |
| | | | | | | [a] Levi 250 [RW] | [a] NOUMED LEVETIRACETAM [VO] |

### levetiracetam 500 mg tablet, 60

8655M NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1 | | 5 | .. | 29.02 | 30.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kevtam 500 [AF] | [a] Levactam [ZS] |
| | | | | | | [a] Levecetam 500 [RZ] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam Mylan [AL] | [a] Levetiracetam SZ [SZ] |
| | | | | | | [a] Levi 500 [RW] | [a] NOUMED LEVETIRACETAM [VO] |

## ▪ LEVETIRACETAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***11077***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

### levetiracetam 100 mg/mL oral liquid, 300 mL

9169N NP

| Max.Qty | Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| ‡1 | | 5 | .. | 75.35 | 30.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kerron [ZS] | [a] Levetiracetam-AFT [AE] |
| | | | | | | [a] Levetiracetam GH [GQ] | |

## ▪ PERAMPANEL

**Authority required (STREAMLINED)**

***4656***

Intractable partial epileptic seizures

Treatment Phase: Initial

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Treatment criteria:**

- Must be treated by a neurologist.

**perampanel 2 mg tablet, 7**

10157N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *48.13 | 30.00 | Fycompa [EI] |

## ▪ PERAMPANEL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4658***

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 6 mg tablet, 28**

10163X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 229.39 | 30.00 | Fycompa [EI] |

**perampanel 8 mg tablet, 28**

10160R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 10 mg tablet, 28**

10151G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 12 mg tablet, 28**

10159Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 4 mg tablet, 28**

10162W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 155.59 | 30.00 | Fycompa [EI] |

## ▪ PERAMPANEL

**Note** No applications for increased maximum quantities will be authorised.

**Authority required (STREAMLINED)**

***7815***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, **AND**
- The treatment must be for dose titration purposes.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 2 mg tablet, 7**

11436X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *48.13 | 30.00 | Fycompa [EI] |

## ▪ PERAMPANEL

**Note** No applications for increased maximum quantities will be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***7789***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 6 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11407J NP | 1 | 2 | .. | 229.39 | 30.00 | Fycompa [EI] |

**perampanel 8 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11429M NP | 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11428L NP | 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 12 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11409L NP | 1 | 5 | .. | 303.16 | 30.00 | Fycompa [EI] |

**perampanel 4 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11418Y NP | 1 | 2 | .. | 155.59 | 30.00 | Fycompa [EI] |

## ▪ STIRIPENTOL

**Authority required (STREAMLINED)**

***11642***

Severe myoclonic epilepsy in infancy (Dravet syndrome)

**Clinical criteria:**

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

**stiripentol 250 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12103B | 2 | 3 | .. | *669.55 | 30.00 | Diacomit [EU] |

**stiripentol 250 mg powder for oral liquid, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12106E | 2 | 3 | .. | *669.55 | 30.00 | Diacomit [EU] |

**stiripentol 500 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12107F | 2 | 3 | .. | *1295.43 | 30.00 | Diacomit [EU] |

**stiripentol 500 mg powder for oral liquid, 60 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12088F | 2 | 3 | .. | *1295.43 | 30.00 | Diacomit [EU] |

## ▪ SULTHIAME

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sulthiame 200 mg tablet, 200**

2100M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 162.85 | 30.00 | Ospolot [FF] |

NP

**sulthiame 50 mg tablet, 200**

2099L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 69.15 | 30.00 | Ospolot [FF] |

NP

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5516***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**topiramate 200 mg tablet, 60**

8166T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 35.75 | 30.00 | [a] APO-Topiramate [TX]<br>[a] NOUMED TOPIRAMATE [VO]<br>[a] Tamate [AF]<br>[a] Topiramate Sandoz [SZ] | [a] Epiramax 200 [RW]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC] |

NP

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5173***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

**topiramate 15 mg capsule, 60**

8371N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 24.30 | 25.70 | Topamax Sprinkle [JC] |

NP

**topiramate 25 mg capsule, 60**

8372P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 22.30 | 23.70 | Topamax Sprinkle [JC] |

NP

**topiramate 50 mg capsule, 60**

8520K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 28.52 | 29.92 | Topamax Sprinkle [JC] |

NP

## ▪ TOPIRAMATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5516***

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)**

***5325***

Migraine

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 100 mg tablet, 60**

8165R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.54 | 27.94 | [a] APO-Topiramate [TX]<br>[a] NOUMED TOPIRAMATE [VO]<br>[a] Tamate [AF]<br>[a] Topiramate Sandoz [SZ] | [a] Epiramax 100 [RW]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC] |

**topiramate 25 mg tablet, 60**

8163P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.28 | 19.68 | [a] APO-Topiramate [TX]<br>[a] NOUMED TOPIRAMATE [VO]<br>[a] Tamate [AF]<br>[a] Topiramate Sandoz [SZ] | [a] Epiramax 25 [RW]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC] |

**topiramate 50 mg tablet, 60**

8164Q (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.60 | 23.00 | [a] APO-Topiramate [TX]<br>[a] NOUMED TOPIRAMATE [VO]<br>[a] Tamate [AF]<br>[a] Topiramate Sandoz [SZ] | [a] Epiramax 50 [RW]<br>[a] RBX Topiramate [RA]<br>[a] Topamax [JC] |

## ▪ ZONISAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4928***

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**zonisamide 25 mg capsule, 56**

9388D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 24.35 | 25.75 | Zonegran [GH] |

**zonisamide 50 mg capsule, 56**

9389E (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 31.94 | 30.00 | Zonegran [GH] |

**zonisamide 100 mg capsule, 56**

9390F (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *76.13 | 30.00 | Zonegran [GH] |

# ▪ ANTI-PARKINSON DRUGS

## ANTICHOLINERGIC AGENTS

*Tertiary amines*

## ▪ TRIHEXYPHENIDYL (BENZHEXOL)

**trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200**

1109J

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 18.20 | 19.60 | Artane [RW] |

**trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200**

1110K

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | .. | 21.90 | 23.30 | Artane [RW] |

*Ethers of tropine or tropine derivatives*

## ▪ BENZATROPINE

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

11249C

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 118.14 | 30.00 | Benzatropine Injection [FF] |

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

11255J

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 118.14 | 30.00 | Benzatropine Injection [FF] |

**benzatropine mesilate 2 mg tablet, 60**

2362H

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 17.85 | 19.25 | Benztrop [FF] |

# DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

## ▪ LEVODOPA + BENSERAZIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 100 mg + benserazide 25 mg capsule, 100**

2225D

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.06 | 30.00 | Madopar 125 [RO] |

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

2231K

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 32.62 | 30.00 | Madopar HBS [RO] |

**levodopa 200 mg + benserazide 50 mg capsule, 100**

2226E

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 39.02 | 30.00 | Madopar [RO] |

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

2227F

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.70 | 26.10 | Madopar 62.5 [RO] |

**levodopa 100 mg + benserazide 25 mg dispersible tablet, 100**

8219N

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 34.80 | 30.00 | Madopar Rapid 125 [RO] |

**levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100**

8218M

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.70 | 26.10 | Madopar Rapid 62.5 [RO] |

**levodopa 100 mg + benserazide 25 mg tablet, 100**

2229H

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.06 | 30.00 | Madopar 125 [RO] |

**levodopa 200 mg + benserazide 50 mg tablet, 100**

2228G

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 39.02 | 30.00 | Madopar [RO] |

## ▪ LEVODOPA + CARBIDOPA

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### levodopa 100 mg + carbidopa 25 mg tablet, 100

1242J

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 31.97 | 30.00 | [a] APO-Levodopa/Carbidopa [TX]<br>[a] SINADOPA 100/25 [RW] | [a] Kinson [AF]<br>[a] Sinemet 100/25 [AL] |

### levodopa 250 mg + carbidopa 25 mg tablet, 100

1245M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 36.40 | 30.00 | [a] APO-Levodopa/Carbidopa [TX]<br>[a] Sinemet [AL] | [a] SINADOPA 250/25 [RW] |

## ▪ LEVODOPA + CARBIDOPA

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

### levodopa 200 mg + carbidopa 50 mg modified release tablet, 100

1255C

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 68.85 | 30.00 | Sinemet CR [AL] |

## ▪ LEVODOPA + CARBIDOPA

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

***10197***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

### levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

11919H

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *5903.09 | 30.00 | Duodopa [VE] |

## ▪ LEVODOPA + CARBIDOPA

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

***10386***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8970D NP | 8 | 5 | .. | *11698.13 | 30.00 | Duodopa [VE] |

## ▪ LEVODOPA + CARBIDOPA + ENTACAPONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8798C NP | 2 | 4 | .. | *198.41 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 100/25/200mg [SZ] |

**levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9345W NP | 2 | 4 | .. | *205.65 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 125/31.25/200mg [SZ] |

**levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8799D NP | 2 | 4 | .. | *216.43 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 150/37.5/200mg [SZ] |

**levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9292C NP | 2 | 4 | .. | *233.01 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 200/50/200mg [SZ] |

**levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8797B NP | 2 | 4 | .. | *180.41 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 50/12.5/200mg [SZ] |

**levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9344T NP | 2 | 4 | .. | *188.33 | 30.00 | [a] Carlevent [TX]<br>[a] Lecteva [TB] | [a] L.C.E. Sandoz [HX]<br>[a] Stalevo 75/18.75/200mg [SZ] |

*Adamantane derivatives*

## ▪ AMANTADINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must not be drug induced.

**amantadine hydrochloride 100 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3016R NP | 1 | 5 | .. | 34.09 | 30.00 | Symmetrel 100 [NV] |

*Dopamine agonists*

## ▪ APOMORPHINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***10844***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12142C NP | 18 | 5 | .. | *7589.43 | 30.00 | Apomine Solution for Infusion [PF] |

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12319J NP | 36 | 5 | .. | *8179.29 | 30.00 | Movapo PFS [TD] |

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12306Q NP | 36 | 5 | .. | *6191.73 | 30.00 | Movapo [TD] |

## ▪ APOMORPHINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***10844***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12133N NP | 20 | 5 | .. | *2750.17 | 30.00 | [a] Apomine Intermittent [PF] |

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12137T NP | 20 | 5 | .. | *2750.17 | 30.00 | [a] Movapo Pen [TD] |

## ▪ BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *32.25 | 30.00 | Parlodel [SZ] |

## ▪ CABERGOLINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**cabergoline 1 mg tablet, 30**

8393R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 49.46 | 30.00 | Cabaser [PF] |

**cabergoline 2 mg tablet, 30**

8394T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.87 | 30.00 | Cabaser [PF] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**pramipexole dihydrochloride monohydrate 1 mg tablet, 100**

9153R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 77.50 | 30.00 | [a] APO-Pramipexole [TX] | [a] Sifrol [BY] |
| | | | | | [a] Simipex 1 [RW] | [a] Simpral [AF] |

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

9151P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 16.44 | 17.84 | [a] APO-Pramipexole [TX] | [a] Sifrol [BY] |
| | | | | | [a] Simipex 0.125 [RW] | [a] Simpral [AF] |

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

9152Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 27.77 | 29.17 | [a] APO-Pramipexole [TX] | [a] Sifrol [BY] |
| | | | | | [a] Simipex 0.25 [RW] | [a] Simpral [AF] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30**

3418X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 20.75 | 22.15 | [a] APO-Pramipexole ER [TX] | [a] Sifrol ER [BY] |
| | | | | | [a] SIMIPEX XR [RW] | |

**pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30**

3419Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 28.26 | 29.66 | [a] APO-Pramipexole ER [TX] | [a] Sifrol ER [BY] |
| | | | | | [a] SIMIPEX XR [RW] | |

**pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30**

| 3420B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 43.53 | 30.00 | [a] APO-Pramipexole ER [TX]<br>[a] SIMIPEX XR [RW] | [a] Sifrol ER [BY] |

**pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30**

| 5143Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.79 | 30.00 | [a] APO-Pramipexole ER [TX]<br>[a] SIMIPEX XR [RW] | [a] Sifrol ER [BY] |

**pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30**

| 3421C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 79.62 | 30.00 | [a] APO-Pramipexole ER [TX]<br>[a] SIMIPEX XR [RW] | [a] Sifrol ER [BY] |

**pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30**

| 5145T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 94.88 | 30.00 | [a] APO-Pramipexole ER [TX]<br>[a] SIMIPEX XR [RW] | [a] Sifrol ER [BY] |

**pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30**

| 3422D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 112.93 | 30.00 | [a] APO-Pramipexole ER [TX]<br>[a] SIMIPEX XR [RW] | [a] Sifrol ER [BY] |

## ▪ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

| 9393J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 16.44 | 17.84 | [a] Sifrol [BY] | [a] Simipex 0.125 [RW] |

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

| 9394K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | .. | 27.77 | 29.17 | [a] Sifrol [BY] | [a] Simipex 0.25 [RW] |

## ▪ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 4 mg/24 hours patch, 28**

| 2384L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 90.48 | 30.00 | Neupro [UC] |

**rotigotine 6 mg/24 hours patch, 28**

| 2410W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 100.92 | 30.00 | Neupro [UC] |

**rotigotine 8 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11140H | 1 | 5 | .. | 110.76 | 30.00 | Neupro [UC] |

## ▪ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 2 mg/24 hours patch, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2385M | 1 | 5 | .. | 71.12 | 30.00 | Neupro [UC] |

*Monoamine oxidase B inhibitors*

## ▪ RASAGILINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Parkinson disease

**rasagiline 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1952R NP | 1 | 5 | .. | 55.59 | 30.00 | [a] Alziras [RW]<br>[a] Rasagiline Lupin [HQ]<br>[a] Rasagiline-Teva [EV] | [a] Pharmacor Rasagiline [CR]<br>[a] Rasagiline Sandoz [SZ] |
| | | | [B]3.60 | 59.19 | 30.00 | [a] Azilect [TB] | |

## ▪ SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**safinamide 50 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11656L NP | 1 | 5 | .. | 65.34 | 30.00 | Xadago [CS] |

**safinamide 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11666B NP | 1 | 5 | .. | 117.93 | 30.00 | Xadago [CS] |

## ▪ SELEGILINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Late stage Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**selegiline hydrochloride 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1973W NP | 1 | 5 | .. | 41.78 | 30.00 | Eldepryl [OX] |

*Other dopaminergic agents*

## ▪ ENTACAPONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**entacapone 200 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8367J NP | 2 | 4 | .. | *178.77 | 30.00 | Comtan [SZ] |

## ▪ OPICAPONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**opicapone 50 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13206C NP | 1 | 5 | .. | 151.22 | 30.00 | Ongentys [XY] |

# ▪ PSYCHOLEPTICS

## ANTIPSYCHOTICS

*Phenothiazines with aliphatic side-chain*

## ▪ CHLORPROMAZINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**chlorpromazine hydrochloride 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1197B NP | 1 | 5 | .. | 16.73 | 18.13 | Largactil [IX] |

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1195X NP | 1 | .. | .. | 22.91 | 24.31 | Largactil [IX] |

**chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1201F NP | ‡1 | 5 | .. | 17.58 | 18.98 | Largactil [IX] |

**chlorpromazine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1199D NP | 1 | 5 | .. | 20.76 | 22.16 | Largactil [IX] |

*Phenothiazines with piperidine structure*

## ▪ PERICIAZINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**periciazine 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3053Q NP | 1 | 5 | .. | 19.19 | 20.59 | Neulactil [IX] |

**periciazine 2.5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3052P NP | 1 | 5 | .. | 16.20 | 17.60 | Neulactil [IX] |

*Butyrophenone derivatives*

## ▪ HALOPERIDOL

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

2768Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 24.19 | 25.59 | Serenace [AS] |

**haloperidol 2 mg/mL oral liquid, 100 mL**

2763K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 23.51 | 24.91 | Serenace [AS] |

**haloperidol 1.5 mg tablet, 100**

2767P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.81 | 18.21 | Serenace [AS] |

**haloperidol 5 mg tablet, 50**

2770T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.67 | 18.07 | Serenace [AS] |

**haloperidol 500 microgram tablet, 100**

2761H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.46 | 17.86 | Serenace [AS] |

## ▪ HALOPERIDOL DECANOATE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules**

2766N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 45.98 | 30.00 | Haldol decanoate [JC] |

**haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules**

2765M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 29.44 | 30.00 | Haldol decanoate [JC] |

*Indole derivatives*

## ▪ LURASIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**lurasidone hydrochloride 40 mg tablet, 30**

10526B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 42.54 | 30.00 | [a] APO-Lurasidone [TX] | [a] Ardix Lurasidone [RX] |
| | | | | | [a] Latuda [SE] | [a] Lavione [AF] |
| | | | | | [a] Lurasidone Lupin [GQ] | [a] Lurasidone Sandoz [SZ] |
| | | | | | [a] LURASIDONE SUN [RA] | [a] Pharmacor Lurasidone [CR] |

**lurasidone hydrochloride 80 mg tablet, 30**

10529E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 72.08 | 30.00 | [a] APO-Lurasidone [TX] | [a] Ardix Lurasidone [RX] |
| | | | | | [a] Latuda [SE] | [a] Lavione [AF] |
| | | | | | [a] Lurasidone Lupin [GQ] | [a] Lurasidone Sandoz [SZ] |
| | | | | | [a] LURASIDONE SUN [RA] | [a] Pharmacor Lurasidone [CR] |

## ▪ ZIPRASIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**Authority required (STREAMLINED)**

***5742***

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**ziprasidone 20 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9070J NP | 1 | 5 | .. | 48.06 | 30.00 | [a] APO-Ziprasidone [TX]<br>[a] Ziprasidone GH [GQ] | [a] Zeldox [UJ]<br>[a] ZIPROX [RW] |

**ziprasidone 40 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9071K NP | 1 | 5 | .. | 83.27 | 30.00 | [a] APO-Ziprasidone [TX]<br>[a] Ziprasidone GH [GQ] | [a] Zeldox [UJ]<br>[a] ZIPROX [RW] |

**ziprasidone 60 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9072L NP | 1 | 5 | .. | 118.27 | 30.00 | [a] APO-Ziprasidone [TX]<br>[a] Ziprasidone GH [GQ] | [a] Zeldox [UJ]<br>[a] ZIPROX [RW] |

**ziprasidone 80 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9073M NP | 1 | 5 | .. | 155.23 | 30.00 | [a] APO-Ziprasidone [TX]<br>[a] Ziprasidone GH [GQ] | [a] Zeldox [UJ]<br>[a] ZIPROX [RW] |

*Thioxanthene derivatives*

## ▪ FLUPENTIXOL DECANOATE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2257T NP | 1 | .. | .. | 50.34 | 30.00 | Fluanxol Concentrated Depot [LU] |

**flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2255Q NP | 1 | .. | .. | 25.24 | 26.64 | Fluanxol Depot [LU] |

## ▪ ZUCLOPENTHIXOL DECANOATE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8097E NP | 1 | .. | .. | 31.09 | 30.00 | Clopixol Depot [LU] |

*Diazepines, oxazepines, thiazepines and oxepines*

## ▪ ASENAPINE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**Authority required (STREAMLINED)**

***5773***

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**

***5719***
Bipolar I disorder
**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

**asenapine 10 mg sublingual wafer, 60**

5141N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 224.32 | 30.00 | Saphris [OQ] |

**asenapine 5 mg sublingual wafer, 60**

5140M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 137.76 | 30.00 | Saphris [OQ] |

## ▪ OLANZAPINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5856***
Schizophrenia
**Authority required (STREAMLINED)**
***5869***
Bipolar I disorder
**Clinical criteria:**
- The treatment must be maintenance therapy.

**olanzapine 2.5 mg tablet, 28**

8170B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.48 | 17.88 | [a] NOUMED OLANZAPINE [VO]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 2.5 [ZS]<br>[a] Zypine [AF] | [a] Olanzapine APOTEX [GX]<br>[a] Olanzapine Sandoz [SZ]<br>[a] PRYZEX [RW] |
| | | [B]7.83 | 24.31 | 17.88 | [a] Zyprexa [LY] | |

**olanzapine 5 mg tablet, 28**

8185T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.40 | 18.80 | [a] NOUMED OLANZAPINE [VO]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 5 [ZS]<br>[a] Zypine [AF] | [a] Olanzapine APOTEX [GX]<br>[a] Olanzapine Sandoz [SZ]<br>[a] PRYZEX [RW] |
| | | [B]10.17 | 27.57 | 18.80 | [a] Zyprexa [LY] | |

**olanzapine 7.5 mg tablet, 28**

8186W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 19.09 | 20.49 | [a] NOUMED OLANZAPINE [VO]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 7.5 [ZS]<br>[a] Zypine [AF] | [a] Olanzapine APOTEX [GX]<br>[a] Olanzapine Sandoz [SZ]<br>[a] PRYZEX [RW] |
| | | [B]5.87 | 24.96 | 20.49 | [a] Zyprexa [LY] | |

**olanzapine 10 mg tablet, 28**

8187X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.11 | 22.51 | [a] NOUMED OLANZAPINE [VO]<br>[a] Olanzapine RBX [RA]<br>[a] Ozin 10 [ZS]<br>[a] Zypine [AF] | [a] Olanzapine APOTEX [GX]<br>[a] Olanzapine Sandoz [SZ]<br>[a] PRYZEX [RW] |
| | | [B]5.86 | 26.97 | 22.51 | [a] Zyprexa [LY] | |

## ▪ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5856***
Schizophrenia

**Authority required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 5 mg orally disintegrating tablet, 28**

3381Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 17.40 | 18.80 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine ODT generichealth 5 [GQ] |
| | | | | | [a] Olanzapine Sandoz ODT 5 [SZ] | [a] PRYZEX ODT [RW] |

**olanzapine 5 mg wafer, 28**

8433W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 17.40 | 18.80 | [a] Zypine ODT [AF] |
| | | [B]10.17 | 27.57 | 18.80 | [a] Zyprexa Zydis [LY] |

## ▪ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5856***

Schizophrenia

**Authority required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 10 mg orally disintegrating tablet, 28**

3382B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.11 | 22.51 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine ODT generichealth 10 [GQ] |
| | | | | | [a] Olanzapine Sandoz ODT 10 [SZ] | [a] PRYZEX ODT [RW] |

**olanzapine 10 mg wafer, 28**

8434X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 21.11 | 22.51 | [a] Zypine ODT [AF] |
| | | [B]11.86 | 32.97 | 22.51 | [a] Zyprexa Zydis [LY] |

## ▪ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5856***

Schizophrenia

**Authority required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 15 mg orally disintegrating tablet, 28**

3384D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 25.17 | 26.57 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 15 [SZ] |
| | | | | | [a] PRYZEX ODT [RW] | |

**olanzapine 15 mg wafer, 28**

8952E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 25.17 | 26.57 | [a] Zypine ODT [AF] |

| | | | | |
|---|---|---|---|---|
| [B]13.87 | 39.04 | 26.57 | [a] Zyprexa Zydis [LY] | |

## ▪ OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***5856***
Schizophrenia
**Authority required (STREAMLINED)**
***5869***
Bipolar I disorder
**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 20 mg orally disintegrating tablet, 28**

3385E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.24 | 30.00 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 20 [SZ] |
| | | | | | [a] PRYZEX ODT [RW] | |

**olanzapine 20 mg wafer, 28**

8953F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 29.24 | 30.00 | [a] Zypine ODT [AF] |
| | | [B]13.87 | 43.11 | 30.00 | [a] Zyprexa Zydis [LY] |

## ▪ OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4304***
Schizophrenia

**olanzapine 210 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

9294E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *322.69 | 30.00 | Zyprexa Relprevv [LY] |

**olanzapine 300 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

9295F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *520.09 | 30.00 | Zyprexa Relprevv [LY] |

**olanzapine 405 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

9303P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 346.35 | 30.00 | Zyprexa Relprevv [LY] |

## ▪ QUETIAPINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia
**Authority required (STREAMLINED)**
***5611***
Acute mania
**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**
***5639***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**quetiapine 150 mg modified release tablet, 60**

| 5458G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.94 | 26.34 | [a] APX-Quetiapine XR [TY]<br>[a] Tevatiapine XR [TB] | [a] Quetia XR [OW] |
| | | | [B]18.01 | 42.95 | 26.34 | [a] Seroquel XR [AL] | |

**quetiapine 200 mg modified release tablet, 60**

| 9203J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 37.58 | 30.00 | [a] APX-Quetiapine XR [TY]<br>[a] Quetia XR [OW] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |
| | | | [B]11.00 | 48.58 | 30.00 | [a] Seroquel XR [AL] | |

**quetiapine 300 mg modified release tablet, 60**

| 9204K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 44.57 | 30.00 | [a] APX-Quetiapine XR [TY]<br>[a] Quetia XR [OW] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |
| | | | [B]11.00 | 55.57 | 30.00 | [a] Seroquel XR [AL] | |

**quetiapine 400 mg modified release tablet, 60**

| 9205L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 56.04 | 30.00 | [a] APX-Quetiapine XR [TY]<br>[a] Quetia XR [OW] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |
| | | | [B]11.00 | 67.04 | 30.00 | [a] Seroquel XR [AL] | |

**quetiapine 50 mg modified release tablet, 60**

| 9202H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 21.44 | 22.84 | [a] APX-Quetiapine XR [TY]<br>[a] Quetia XR [OW] | [a] QUETIAPINE-AS XR [RW]<br>[a] Tevatiapine XR [TB] |
| | | | [B]11.00 | 32.44 | 22.84 | [a] Seroquel XR [AL] | |

**quetiapine 100 mg tablet, 90**

| 8457D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 24.94 | 26.34 | [a] Kaptan [ZS]<br>[a] Quetia 100 [RW]<br>[a] Quetiapine APOTEX [GX]<br>[a] Quetiapine Sandoz Pharma [HX] | [a] Pharmacor Quetiapine 100 [CR]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine RBX [RA]<br>[a] Syquet [AF] |
| | | | [B]10.99 | 35.93 | 26.34 | [a] Seroquel [AL] | |

**quetiapine 200 mg tablet, 60**

| 8458E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 29.27 | 30.00 | [a] Kaptan [ZS]<br>[a] Quetia 200 [RW]<br>[a] Quetiapine RBX [RA]<br>[a] Syquet [AF] | [a] Pharmacor Quetiapine 200 [CR]<br>[a] Quetiapine APOTEX [GX]<br>[a] Quetiapine Sandoz Pharma [HX] |
| | | | [B]11.00 | 40.27 | 30.00 | [a] Seroquel [AL] | |

**quetiapine 300 mg tablet, 60**

| 8580N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 36.89 | 30.00 | [a] Kaptan [ZS]<br>[a] Quetia 300 [RW]<br>[a] Quetiapine APOTEX [GX]<br>[a] Quetiapine Sandoz Pharma [HX] | [a] Pharmacor Quetiapine 300 [CR]<br>[a] Quetiapine AN [EA]<br>[a] Quetiapine RBX [RA]<br>[a] Syquet [AF] |
| | | | [B]11.00 | 47.89 | 30.00 | [a] Seroquel [AL] | |

## ▪ QUETIAPINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***7916***
Schizophrenia
**Authority required (STREAMLINED)**
***7927***
Acute mania
**Clinical criteria:**
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

**Authority required (STREAMLINED)**
***7893***
Bipolar I disorder
**Clinical criteria:**
- The treatment must be maintenance therapy.

**quetiapine 25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8456C NP | 1 | .. | .. | 17.40 | 18.80 | [a] Kaptan [ZS]<br>[a] Quetia 25 [RW]<br>[a] Quetiapine RBX [RA]<br>[a] Syquet [AF] | [a] Pharmacor Quetiapine 25 [CR]<br>[a] Quetiapine APOTEX [GX]<br>[a] Quetiapine Sandoz Pharma [HX] |
| | | | [B]11.00 | 28.40 | 18.80 | [a] Seroquel [AL] | |

*Benzamides*

## ▪ AMISULPRIDE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**amisulpride 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8594H NP | 1 | 5 | .. | 18.90 | 20.30 | [a] Amisulpride 100 Winthrop [WA]<br>[a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] | [a] Amisulpride Sandoz Pharma [HX]<br>[a] Solian 100 [SW] |

**amisulpride 200 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8595J NP | 1 | 5 | .. | 38.49 | 30.00 | [a] Amisulpride Sandoz Pharma [HX]<br>[a] Solian 200 [SW] | [a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] |

**amisulpride 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8596K NP | 1 | 5 | .. | 59.23 | 30.00 | [a] Amipride 400 [RW]<br>[a] Amisulpride Sandoz Pharma [HX]<br>[a] Solian 400 [SW] | [a] Amisulpride 400 Winthrop [WA]<br>[a] APO-Amisulpride [TX]<br>[a] Sulprix [AF] |

**amisulpride 100 mg/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8736T NP | 2 | 5 | .. | *143.83 | 30.00 | Solian Solution [SW] |

*Other antipsychotics*

## ▪ ARIPIPRAZOLE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10224D NP | 1 | 5 | .. | 292.90 | 30.00 | Abilify Maintena [LU] |

**aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

| 10219W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 364.13 | 30.00 | Abilify Maintena [LU] |

**aripiprazole 15 mg tablet, 30**

| 8718W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 77.50 | 30.00 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripic Aripiprazole [LR]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 30 mg tablet, 30**

| 8720Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 108.69 | 30.00 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole generichealth [HQ]<br>[a] Aripiprazole Sandoz [SZ] | [a] Abyraz [AF]<br>[a] Aripic Aripiprazole [LR]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] |

**aripiprazole 10 mg tablet, 30**

| 8717T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 58.45 | 30.00 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripic Aripiprazole [LR]<br>[a] Aripiprazole Sandoz [SZ] |

**aripiprazole 20 mg tablet, 30**

| 8719X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 91.52 | 30.00 | [a] Abilify [OS]<br>[a] APO-Aripiprazole [TX]<br>[a] Aripiprazole GH [GQ]<br>[a] Tevaripiprazole [TB] | [a] Abyraz [AF]<br>[a] Aripic Aripiprazole [LR]<br>[a] Aripiprazole Sandoz [SZ] |

## ▪ BREXPIPRAZOLE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**brexpiprazole 1 mg tablet, 30**

| 11189X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 138.95 | 30.00 | Rexulti [LU] |

**brexpiprazole 2 mg tablet, 30**

| 11188W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 138.95 | 30.00 | Rexulti [LU] |

**brexpiprazole 3 mg tablet, 30**

| 11190Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 138.95 | 30.00 | Rexulti [LU] |

**brexpiprazole 4 mg tablet, 30**

| 11184P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 138.95 | 30.00 | Rexulti [LU] |

## ▪ CARIPRAZINE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**cariprazine 1.5 mg capsule, 30**

| 12652X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 101.97 | 30.00 | Reagila [CS] |

**cariprazine 3 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12619E NP | 1 | 5 | .. | 101.97 | 30.00 | Reagila [CS] |

**cariprazine 4.5 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12653Y NP | 1 | 5 | .. | 101.97 | 30.00 | Reagila [CS] |

**cariprazine 6 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12622H NP | 1 | 5 | .. | 101.97 | 30.00 | Reagila [CS] |

## ▪ PALIPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**paliperidone 100 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5107T NP | 1 | 5 | .. | 284.16 | 30.00 | Invega Sustenna [JC] |

**paliperidone 150 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5109X NP | 1 | 5 | .. | 284.16 | 30.00 | Invega Sustenna [JC] |

**paliperidone 25 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5100K NP | 1 | 5 | .. | 95.25 | 30.00 | Invega Sustenna [JC] |

**paliperidone 50 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5102M NP | 1 | 5 | .. | 180.74 | 30.00 | Invega Sustenna [JC] |

**paliperidone 75 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5103N NP | 1 | 5 | .. | 232.71 | 30.00 | Invega Sustenna [JC] |

**paliperidone 3 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9140C NP | 1 | 5 | .. | 55.02 | 30.00 | Invega [JC] |

**paliperidone 6 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9141D NP | 1 | 5 | .. | 97.91 | 30.00 | Invega [JC] |

**paliperidone 9 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9142E NP | 1 | 5 | .. | 141.74 | 30.00 | Invega [JC] |

## ▪ PALIPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***13049***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months; OR

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11085K NP | 1 | 1 | .. | 526.23 | 30.00 | Invega Trinza [JC] |

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11072R NP | 1 | 1 | .. | 682.16 | 30.00 | Invega Trinza [JC] |

**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11094X NP | 1 | 1 | .. | 835.40 | 30.00 | Invega Trinza [JC] |

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11066K NP | 1 | 1 | .. | 835.40 | 30.00 | Invega Trinza [JC] |

## ▪ PALIPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***13082***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle; OR
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

**paliperidone 700 mg/3.5 mL modified release injection, 3.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13053B NP | 1 | .. | .. | 1605.96 | 30.00 | Invega Hafyera [JC] |

**paliperidone 1 g/5 mL modified release injection, 5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13046P NP | 1 | .. | .. | 1605.96 | 30.00 | Invega Hafyera [JC] |

## ▪ RISPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**Authority required (STREAMLINED)**

***5907***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

**risperidone 3 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3171X NP | 1 | 5 | .. | 30.81 | 30.00 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Rixadone [AF] | |

**risperidone 4 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3172Y | | | | | | | |
| NP | 1 | 5 | .. | 37.03 | 30.00 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Rispa [RW] | [a] Risperdal [JC] |
| | | | | | | [a] Risperidone generichealth [GQ] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8100H | | | | | | | |
| NP | ‡1 | 5 | .. | 114.52 | 30.00 | [a] Risperdal [JC] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3169T | | | | | | | |
| NP | 1 | 5 | .. | 18.10 | 19.50 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

**risperidone 2 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3170W | | | | | | | |
| NP | 1 | 5 | .. | 24.54 | 25.94 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***6898***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6899***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 1 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9293D NP | ‡1 | 2 | .. | 114.52 | 30.00 | [a] Risperdal [JC] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8789N NP | 1 | 2 | .. | 18.10 | 19.50 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***6897***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6938***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 2 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9079W NP | 1 | 2 | .. | 24.54 | 25.94 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***4246***

Schizophrenia

**Authority required (STREAMLINED)**

***5912***

Bipolar I disorder

**Clinical criteria:**

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8780D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *186.09 | 30.00 | Risperdal Consta [JC] |

**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8781E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *239.89 | 30.00 | Risperdal Consta [JC] |

**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8782F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *293.15 | 30.00 | Risperdal Consta [JC] |

## ▪ RISPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***5903***

Schizophrenia

**risperidone 500 microgram tablet, 20**

1846E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *21.72 | 23.12 | [a] Risperdal [JC] |

**risperidone 500 microgram tablet, 60**

8869T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.73 | 23.13 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

***6898***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

***6899***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 500 microgram tablet, 20**

1842Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 2 | .. | *21.72 | 23.12 | [a] Risperdal [JC] |

**risperidone 500 microgram tablet, 60**

8787L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 21.73 | 23.13 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10020***

Behavioural disturbances

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

**risperidone 1 mg/mL oral liquid, 100 mL**

11874Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 2 | .. | 114.52 | 30.00 | [a] Risperdal [JC] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

11877D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 18.10 | 19.50 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**

- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

**risperidone 1 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11882J NP | ‡1 | 2 | .. | 114.52 | 30.00 | [a] Risperdal [JC] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11879F NP | 1 | 2 | .. | 18.10 | 19.50 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperdal [JC] | [a] Risperidone generichealth [GQ] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***10020***

Behavioural disturbances

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

**risperidone 500 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11872W NP | 3 | 2 | .. | *21.72 | 23.12 | [a] Risperdal [JC] |

**risperidone 500 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11869Q NP | 1 | 2 | .. | 21.73 | 23.13 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ▪ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

**risperidone 500 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11873X NP | 3 | 2 | .. | *21.72 | 23.12 | [a] Risperdal [JC] |

**risperidone 500 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11881H NP | 1 | 2 | .. | 21.73 | 23.13 | [a] APO-Risperidone [TX] | [a] NOUMED RISPERIDONE [VO] |
| | | | | | | [a] Ozidal [RA] | [a] Rispa [RW] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## ANXIOLYTICS

*Benzodiazepine derivatives*

## ▪ ALPRAZOLAM

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**alprazolam 500 microgram tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11187T NP | 1 | .. | .. | 21.54 | 22.94 | [a] Alprax 0.5 [AS] | [a] Kalma 0.5 [AF] |

**alprazolam 1 mg tablet, 10**

| 11186R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 22.08 | 23.48 | [a] Alprax 1 [AS] | [a] Kalma 1 [AF] |

**alprazolam 250 microgram tablet, 10**

| 11205R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 21.08 | 22.48 | Kalma 0.25 [AF] |

## ▪ DIAZEPAM

**diazepam 2 mg tablet, 50**

| 5071X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Diazepam [TX]<br>[a] Valpam 2 [RW] | [a] APX-Diazepam [TY] |
| | | | [B]2.78 | 18.68 | 17.30 | [a] Antenex 2 [AF] | |

**diazepam 5 mg tablet, 50**

| 5072Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.90 | 17.30 | [a] Antenex 5 [AF]<br>[a] APX-Diazepam [TY]<br>[a] Valpam 5 [RW] | [a] APO-Diazepam [TX]<br>[a] NOUMED DIAZEPAM [VO] |
| | | | [B]3.08 | 18.98 | 17.30 | [a] Valium [IX] | |

## ▪ DIAZEPAM

**Authority required**

Chronic spasticity

**Population criteria:**

- Patient must be under 18 years of age.

**diazepam 10 mg/10 mL oral liquid, 100 mL**

| 2669L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | .. | .. | 44.85 | 30.00 | Diazepam Elixir [ON] |

## ▪ DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 2 mg tablet, 50**

| 3161J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.90 | 17.30 | [a] APO-Diazepam [TX]<br>[a] Valpam 2 [RW] | [a] APX-Diazepam [TY] |
| | | | [B]2.78 | 18.68 | 17.30 | [a] Antenex 2 [AF] | |

**diazepam 5 mg tablet, 50**

| 3162K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | .. | .. | 15.90 | 17.30 | [a] Antenex 5 [AF]<br>[a] APX-Diazepam [TY]<br>[a] Valpam 5 [RW] | [a] APO-Diazepam [TX]<br>[a] NOUMED DIAZEPAM [VO] |
| | | | [B]3.08 | 18.98 | 17.30 | [a] Valium [IX] | |

## ▪ OXAZEPAM

**oxazepam 15 mg tablet, 25**

| 5192G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.70 | 17.10 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| 5193H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | .. | .. | 15.70 | 17.10 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | [B]0.84 | 16.54 | 17.10 | [a] Murelax [RW] | |
| | | | [B]3.92 | 19.62 | 17.10 | [a] Serepax [AS] | |

## ▪ OXAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam.

**oxazepam 15 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3132W NP | 1 | .. | .. | 15.70 | 17.10 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3133X NP | 1 | .. | .. | 15.70 | 17.10 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | [B]0.84 | 16.54 | 17.10 | [a] Murelax [RW] | |
| | | | [B]3.92 | 19.62 | 17.10 | [a] Serepax [AS] | |

## ▪ OXAZEPAM

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**oxazepam 15 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3134Y NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3135B NP | 2 | 5 | .. | *18.41 | 19.81 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | [B]1.68 | *20.09 | 19.81 | [a] Murelax [RW] | |
| | | | [B]7.84 | *26.25 | 19.81 | [a] Serepax [AS] | |

# HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

## ▪ NITRAZEPAM

**nitrazepam 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5189D DP | 1 | .. | .. | 15.70 | 17.10 | [a] Alodorm [AF] | [a] Mogadon [IL] |

## ▪ NITRAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam.

**nitrazepam 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2723H NP | 1 | .. | .. | 15.70 | 17.10 | [a] Alodorm [AF] | [a] Mogadon [IL] |

## ▪ NITRAZEPAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] Alodorm [AF] | [a] Mogadon [IL] |

NP

## ▪ TEMAZEPAM

**temazepam 10 mg tablet, 25**

5221T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] APO-Temazepam [TX]<br>[a] Temtabs [LN] | [a] Temaze [AF] |
| | | [B]5.07 | 20.77 | 17.10 | [a] Normison [AS] | |

DP

## ▪ TEMAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

**temazepam 10 mg tablet, 25**

2089Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 15.70 | 17.10 | [a] APO-Temazepam [TX]<br>[a] Temtabs [LN] | [a] Temaze [AF] |
| | | [B]5.07 | 20.77 | 17.10 | [a] Normison [AS] | |

NP

## ▪ TEMAZEPAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

2088X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *18.41 | 19.81 | [a] APO-Temazepam [TX]<br>[a] Temtabs [LN] | [a] Temaze [AF] |

NP

| | | | | | |
|---|---|---|---|---|---|
| [B]10.14 | *28.55 | 19.81 | [a] Normison [AS] | | |

# PSYCHOANALEPTICS

## ANTIDEPRESSANTS

*Non-selective monoamine reuptake inhibitors*

### AMITRIPTYLINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**amitriptyline hydrochloride 25 mg tablet, 50**

2418G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 16.41 | 17.81 | [a] Amitriptyline Alphapharm 25 [MQ] | [a] Amitriptyline Lupin [GQ] |
| | | | | | [a] Amitriptyline Viatris 25 [AL] | [a] APO-Amitriptyline 25 [TX] |
| | | | | | [a] APX-Amitriptyline [TY] | [a] ENTRIP [RW] |
| | | [B]1.82 | 18.23 | 17.81 | [a] Endep 25 [AF] | |

**amitriptyline hydrochloride 50 mg tablet, 50**

2429W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 16.78 | 18.18 | [a] Amitriptyline Lupin [GQ] | [a] Amitriptyline Viatris 50 [AL] |
| | | | | | [a] APO-Amitriptyline 50 [TX] | [a] APX-Amitriptyline [TY] |
| | | | | | [a] ENTRIP [RW] | |
| | | [B]1.82 | 18.60 | 18.18 | [a] Endep 50 [AF] | |

**amitriptyline hydrochloride 10 mg tablet, 50**

2417F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 16.23 | 17.63 | [a] Amitriptyline Lupin [GQ] | [a] Amitriptyline Viatris 10 [AL] |
| | | | | | [a] APO-Amitriptyline 10 [TX] | [a] APX-Amitriptyline [TY] |
| | | | | | [a] ENTRIP [RW] | |
| | | [B]1.82 | 18.05 | 17.63 | [a] Endep 10 [AF] | |

### CLOMIPRAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cataplexy

**Clinical criteria:**

- The condition must be associated with narcolepsy.

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Phobic disorders

**Population criteria:**

- Patient must be an adult.

**clomipramine hydrochloride 25 mg tablet, 50**

1561E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 18.93 | 20.33 | [a] APO-Clomipramine [TX] | [a] Placil [AF] |
| | | [B]4.41 | 23.34 | 20.33 | [a] Anafranil 25 [PB] | |

### DOSULEPIN (DOTHIEPIN)

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**dosulepin (dothiepin) hydrochloride 25 mg capsule, 50**

1357K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 16.29 | 17.69 | [a] Dosulepin Mylan [AL] | [a] Dosulepin Viatris [MQ] |
| | | [B]1.81 | 18.10 | 17.69 | [a] Dothep 25 [AF] | |

**dosulepin (dothiepin) hydrochloride 75 mg tablet, 30**

1358L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 16.29 | 17.69 | [a] Dosulepin Viatris 75 [AL] |
| | | [B]1.81 | 18.10 | 17.69 | [a] Dothep 75 [AF] |

## ▪ IMIPRAMINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### imipramine hydrochloride 10 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2420J NP | 1 | 2 | .. | 17.37 | 18.77 | Tofranil 10 [GH] |

## ▪ IMIPRAMINE

**Note** Pharmaceutical benefits that have the form imipramine hydrochloride 25 mg tablet in a pack size of 50 can be substituted for a pack size of 100 in the case of a shortage.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### imipramine hydrochloride 25 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12113M NP | 0.5 | 2 | .. | *27.16 | 28.56 | [a] Imipramine (Leading) [QY] |

### imipramine hydrochloride 25 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2421K NP | 1 | 2 | .. | 20.63 | 22.03 | [a] Tofranil 25 [GH] |

## ▪ NORTRIPTYLINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depression
**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**
Major depression
**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy is contraindicated.

### nortriptyline 10 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2522R NP | 1 | 2 | .. | 16.95 | 18.35 | [a] NortriTABS 10 mg [GH] |
| | | | [B]0.50 | 17.45 | 18.35 | [a] Allegron [RW] |

### nortriptyline 25 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2523T NP | 1 | 2 | .. | 17.86 | 19.26 | [a] NortriTABS 25 mg [GH] |
| | | | [B]1.00 | 18.86 | 19.26 | [a] Allegron [RW] |

*Selective serotonin reuptake inhibitors*

## ▪ CITALOPRAM

**Restricted benefit**
Major depressive disorders

### citalopram 10 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8702B NP | 1 | 5 | .. | 15.90 | 17.30 | [a] Celapram [AF]<br>[a] Talam [RW] | [a] Citalopram AN [EF] |

### citalopram 20 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8220P NP | 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Citalopram [TX]<br>[a] Celapram [AF]<br>[a] Citalopram Sandoz [SZ]<br>[a] Talam [RW] | [a] APX-Citalopram [TY]<br>[a] Citalopram AN [EA]<br>[a] NOUMED CITALOPRAM [VO] |
| | | | [B]12.95 | 28.85 | 17.30 | [a] Cipramil [LU] | |

**citalopram 40 mg tablet, 28**

8703C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.94 | 17.34 | [a] APO-Citalopram [TX]<br>[a] Citalopram AN [EA]<br>[a] NOUMED CITALOPRAM [VO] | [a] Celapram [AF]<br>[a] Citalopram Sandoz [SZ]<br>[a] Talam [RW] |

## ▪ ESCITALOPRAM

**Restricted benefit**

Major depressive disorders

**escitalopram 10 mg tablet, 28**

8700X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Escitalopram [TX]<br>[a] Blooms the Chemist Escitalopram [IB]<br>[a] Escitalopram GH [HQ]<br>[a] Esipram [CF]<br>[a] LoxaLate [AF] | [a] APX-Escitalopram [TY]<br>[a] Cilopam-S [ZS]<br>[a] Escitalopram Sandoz [HX]<br>[a] Lexam 10 [RW]<br>[a] NOUMED ESCITALOPRAM [VO] |
| | | [B]13.98 | 29.88 | 17.30 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

8701Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Escitalopram [TX]<br>[a] Blooms the Chemist Escitalopram [IB]<br>[a] Escitalopram GH [HQ]<br>[a] Esipram [CF]<br>[a] LoxaLate [AF] | [a] APX-Escitalopram [TY]<br>[a] Cilopam-S [ZS]<br>[a] Escitalopram Sandoz [HX]<br>[a] Lexam 20 [RW]<br>[a] NOUMED ESCITALOPRAM [VO] |
| | | [B]14.33 | 30.23 | 17.30 | [a] Lexapro [LU] | |

## ▪ ESCITALOPRAM

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

9432K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Escitalopram [TX]<br>[a] Escitalopram GH [HQ]<br>[a] Esipram [CF] | [a] APX-Escitalopram [TY]<br>[a] Escitalopram Sandoz [HX]<br>[a] LoxaLate [AF] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] NOUMED ESCITALOPRAM [VO] | |
| | | [B]13.98 | 29.88 | 17.30 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

9433L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Escitalopram [TX]<br>[a] Escitalopram GH [HQ]<br>[a] Esipram [CF] | [a] APX-Escitalopram [TY]<br>[a] Escitalopram Sandoz [HX]<br>[a] NOUMED ESCITALOPRAM [VO] |
| | | [B]14.33 | 30.23 | 17.30 | [a] Lexapro [LU] | |

## ▪ ESCITALOPRAM

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

10181W

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 38.96 | 30.00 | Lexapro [LU] |

## ▪ FLUOXETINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

1434L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 16.90 | 18.30 | [a] APO-Fluoxetine [TX]<br>[a] FLUOTEX [RF]<br>[a] Fluoxetine generichealth [GQ]<br>[a] NOUMED FLUOXETINE [VO] | [a] BTC Fluoxetine [JB]<br>[a] Fluoxetine APOTEX [TY]<br>[a] Fluoxetine Sandoz [SZ]<br>[a] Zactin [AF] |
| | | [B]1.10 | 18.00 | 18.30 | [a] Prozac 20 [LY] | |

**fluoxetine 20 mg tablet, 28**

8270G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 16.90 | 18.30 | Zactin Tablet [AF] |

## ▪ FLUVOXAMINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

### fluvoxamine maleate 100 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8174F NP | 1 | 5 | .. | 21.56 | 22.96 | [a] APO-Fluvoxamine [TX]<br>[a] Movox 100 [AF] | [a] Faverin 100 [RW] |
| | | | [B]3.50 | 25.06 | 22.96 | [a] Luvox [GO] | |

### fluvoxamine maleate 50 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8512B NP | 1 | 5 | .. | 18.66 | 20.06 | [a] APO-Fluvoxamine [TX]<br>[a] Movox 50 [AL] | [a] Faverin 50 [RW] |
| | | | [B]3.49 | 22.15 | 20.06 | [a] Luvox [GO] | |

## ▪ PAROXETINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

### paroxetine 20 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2242B NP | 1 | 5 | .. | 16.90 | 18.30 | [a] APO-Paroxetine [TX]<br>[a] Blooms The Chemist Paroxetine [BG]<br>[a] Noumed Paroxetine [VO]<br>[a] Paroxetine GH [GQ]<br>[a] Paxtine [AF] | [a] APX-Paroxetine [TY]<br>[a] Extine 20 [RW]<br>[a] Paroxetine AN [EA]<br>[a] Paroxetine Sandoz [SZ] |
| | | | [B]2.43 | 19.33 | 18.30 | [a] Aropax [AS] | |

## ▪ SERTRALINE

**Restricted benefit**

Major depressive disorders

### sertraline 100 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2237R NP | 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Sertraline [TX]<br>[a] NOUMED SERTRALINE [VO]<br>[a] Sertraline AN [EA]<br>[a] Sertraline Sandoz [SZ] | [a] Eleva 100 [AF]<br>[a] Sertra 100 [RW]<br>[a] Sertraline generichealth [GQ]<br>[a] Setrona [RA] |
| | | | [B]5.58 | 21.48 | 17.30 | [a] Zoloft [UJ] | |

### sertraline 50 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2236Q NP | 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Sertraline [TX]<br>[a] NOUMED SERTRALINE [VO]<br>[a] Sertraline AN [EA]<br>[a] Sertraline Sandoz [SZ] | [a] Eleva 50 [AF]<br>[a] Sertra 50 [RW]<br>[a] Sertraline generichealth [GQ]<br>[a] Setrona [RA] |
| | | | [B]5.58 | 21.48 | 17.30 | [a] Zoloft [UJ] | |

## ▪ SERTRALINE

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

### sertraline 100 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8837D NP | 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Sertraline [TX]<br>[a] NOUMED SERTRALINE [VO]<br>[a] Sertraline AN [EA]<br>[a] Sertraline Sandoz [SZ] | [a] Eleva 100 [AF]<br>[a] Sertra 100 [RW]<br>[a] Sertraline generichealth [GQ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | [B]5.58 | 21.48 | 17.30 | [a] Zoloft [UJ] | |

**sertraline 50 mg tablet, 30**

8836C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 15.90 | 17.30 | [a] APO-Sertraline [TX] | [a] Eleva 50 [AF] |
| | | | | | [a] NOUMED SERTRALINE [VO] | [a] Sertra 50 [RW] |
| | | | | | [a] Sertraline AN [EA] | [a] Sertraline generichealth [GQ] |
| | | | | | [a] Sertraline Sandoz [SZ] | |
| | | [B]5.58 | 21.48 | 17.30 | [a] Zoloft [UJ] | |

*Monoamine oxidase inhibitors, non-selective*

## ▪ PHENELZINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

Depression

**Clinical criteria:**

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**phenelzine 15 mg tablet, 60**

13148B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *173.85 | 30.00 | Nardil (Canada) [DZ] |

**phenelzine 15 mg tablet, 100**

2856H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 66.79 | 30.00 | Nardil [LM] |

## ▪ TRANYLCYPROMINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**tranylcypromine 10 mg tablet, 50**

2444P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 51.31 | 30.00 | Parnate [GH] |

*Monoamine oxidase A inhibitors*

## ▪ MOCLOBEMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**moclobemide 150 mg tablet, 60**

1900B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 21.37 | 22.77 | [a] Amira 150 [AF] | [a] APO-Moclobemide [TX] |
| | | | | | [a] Clobemix [ED] | [a] Moclobemide AN [EA] |
| | | | | | [a] Moclobemide Sandoz [SZ] | |
| | | [B]2.58 | 23.95 | 22.77 | [a] Aurorix [GO] | |

**moclobemide 300 mg tablet, 60**

8003F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.97 | 28.37 | [a] Amira 300 [AF] | [a] APO-Moclobemide [TX] |
| | | | | | [a] Clobemix [ED] | [a] Moclobemide AN [EA] |
| | | | | | [a] Moclobemide Sandoz [SZ] | |
| | | [B]2.58 | 29.55 | 28.37 | [a] Aurorix 300 mg [GO] | |

*Other antidepressants*

## ▪ DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**desvenlafaxine 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10231L NP | 1 | 5 | .. | 23.12 | 24.52 | [a] Desfax [AF]<br>[a] Desvenlafaxine Actavis [EA] | [a] DESVEN [RW]<br>[a] Desvenlafaxine Sandoz [SZ] |

**desvenlafaxine 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10245F NP | 1 | 5 | .. | 23.12 | 24.52 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 100 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9367B NP | 1 | 5 | .. | 23.12 | 24.52 | [a] Pristiq [PF] |

## ▪ DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**desvenlafaxine 50 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10234P NP | 1 | 5 | .. | 21.24 | 22.64 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 50 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10241B NP | 1 | 5 | .. | 21.24 | 22.64 | [a] Desfax [AF]<br>[a] Desvenlafaxine Actavis [EA] | [a] DESVEN [RW]<br>[a] Desvenlafaxine Sandoz [SZ] |

**desvenlafaxine 50 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9366Y NP | 1 | 5 | .. | 21.24 | 22.64 | [a] Pristiq [PF] |

## ▪ DULOXETINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**duloxetine 30 mg enteric capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9155W NP | 1 | .. | .. | 17.26 | 18.66 | [a] APO-Duloxetine [TX]<br>[a] Duloxetine Sandoz [HX]<br>[a] DYTREX 30 [RW] | [a] Duloxecor [CR]<br>[a] Duloxetine Sandoz 30 [SZ]<br>[a] Tixol [AL] |
| | | | [B]15.24 | 32.50 | 18.66 | [a] Cymbalta [LY] | |

**duloxetine 60 mg enteric capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9156X NP | 1 | 5 | .. | 17.78 | 19.18 | [a] APO-Duloxetine [TX]<br>[a] Duloxetine Sandoz [HX]<br>[a] DYTREX 60 [RW] | [a] Duloxecor [CR]<br>[a] Duloxetine Sandoz 60 [SZ]<br>[a] Tixol [AL] |
| | | | [B]15.25 | 33.03 | 19.18 | [a] Cymbalta [LY] | |

## ▪ LITHIUM CARBONATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lithium carbonate 250 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3059B NP | 1 | 2 | .. | 29.91 | 30.00 | Lithicarb [AS] |

**lithium carbonate 450 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8290H NP | 2 | 2 | .. | *53.61 | 30.00 | Quilonum SR [AS] |

## ▪ MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Severe depression

**mianserin hydrochloride 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1627P NP | 1 | 5 | .. | 20.79 | 22.19 | Lumin 10 [AF] |

**mianserin hydrochloride 20 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1628Q NP | 1 | 5 | .. | 29.44 | 30.00 | Lumin 20 [AF] |

## ▪ MIRTAZAPINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**mirtazapine 15 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9365X NP | 1 | 5 | .. | 16.13 | 17.53 | [a] APO-Mirtazapine [TX] | [a] APX-Mirtazapine [TY] |
| | | | | | | [a] Axit 15 [AF] | [a] Blooms The Chemist Mirtazapine [BG] |
| | | | | | | [a] MIRTANZA [RF] | [a] Mirtazapine Sandoz [SZ] |

**mirtazapine 15 mg orally disintegrating tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8855C NP | 1 | 5 | .. | 17.25 | 18.65 | [a] MIRTANZA ODT [RF] | [a] Mirtazapine AN ODT [EA] |

**mirtazapine 30 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8513C NP | 1 | 5 | .. | 16.90 | 18.30 | [a] APO-Mirtazapine [TX] | [a] APX-Mirtazapine [TY] |
| | | | | | | [a] Axit 30 [AF] | [a] Blooms The Chemist Mirtazapine [BG] |
| | | | | | | [a] MIRTANZA [RF] | [a] Mirtazapine Sandoz [SZ] |
| | | | | | | [a] Mirtazon [RW] | [a] NOUMED MIRTAZAPINE [VO] |
| | | | [B]5.86 | 22.76 | 18.30 | [a] Avanza [AL] | |

**mirtazapine 30 mg orally disintegrating tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8856D NP | 1 | 5 | .. | 17.77 | 19.17 | [a] MIRTANZA ODT [RF] | [a] Mirtazapine AN ODT [EA] |

**mirtazapine 45 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8883M NP | 1 | 5 | .. | 18.15 | 19.55 | [a] APO-Mirtazapine [TX] | [a] APX-Mirtazapine [TY] |
| | | | | | | [a] Axit 45 [AF] | [a] Blooms The Chemist Mirtazapine [BG] |
| | | | | | | [a] MIRTANZA [RF] | [a] Mirtazapine Sandoz [SZ] |
| | | | | | | [a] Mirtazon [RW] | [a] NOUMED MIRTAZAPINE [VO] |

**mirtazapine 45 mg orally disintegrating tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8857E NP | 1 | 5 | .. | 20.06 | 21.46 | [a] MIRTANZA ODT [RF] | [a] Mirtazapine AN ODT [EA] |

## ▪ REBOXETINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**reboxetine 4 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8583R NP | 1 | 5 | .. | 39.70 | 30.00 | Edronax [PF] |

## ▪ VENLAFAXINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**venlafaxine 150 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8302Y NP | 1 | 5 | .. | 17.40 | 18.80 | [a] APO-Venlafaxine XR [TX] | [a] Blooms the Chemist Venlafaxine XR [IB] |
| | | | | | | [a] Elaxine SR 150 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | [B]1.96 | 19.36 | 18.80 | [a] Efexor-XR [UJ] | |

**venlafaxine 37.5 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8868R NP | 1 | .. | .. | 16.12 | 17.52 | [a] Efexor-XR [UJ] | [a] Elaxine SR 37.5 [RW] |

**venlafaxine 75 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8301X NP | 1 | 5 | .. | 16.90 | 18.30 | [a] APO-Venlafaxine XR [TX] | [a] Blooms the Chemist Venlafaxine XR [IB] |
| | | | | | | [a] Elaxine SR 75 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | [B]2.00 | 18.90 | 18.30 | [a] Efexor-XR [UJ] | |

# PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

*Centrally acting sympathomimetics*

## ▪ ARMODAFINIL

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Narcolepsy

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with modafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**armodafinil 50 mg tablet, 30**

10922W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *103.09 | 30.00 | Nuvigil [TB] |

**armodafinil 150 mg tablet, 30**

10912H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 149.89 | 30.00 | Nuvigil [TB] |

**armodafinil 250 mg tablet, 30**

10919Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 244.48 | 30.00 | Nuvigil [TB] |

## ▪ ATOMOXETINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***7876***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority required (STREAMLINED)**

***7890***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**atomoxetine 10 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9092M | 2 | 5 | .. | *74.67 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 100 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9290Y | 1 | 5 | .. | 53.08 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 18 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9093N | 2 | 5 | .. | *74.67 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 25 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9094P | 2 | 5 | .. | *74.67 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 40 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9095Q | 2 | 5 | .. | *74.67 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 60 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9096R | 2 | 5 | .. | *74.67 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 80 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9289X | 1 | 5 | .. | 53.08 | 30.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

## ▪ DEXAMFETAMINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority required**

Narcolepsy

**dexamfetamine sulfate 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1165H | 1 | 5 | .. | 24.57 | 25.97 | Aspen Pharma Pty Ltd [AS] |

NP

## ▪ LISDEXAMFETAMINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 70 mg with this drug.

**Population criteria:**

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**lisdexamfetamine dimesilate 30 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10486X NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 70 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10492F NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 40 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11898F NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 60 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11897E NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 50 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10474G NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 20 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11884L NP | 1 | 5 | .. | 99.99 | 30.00 | Vyvanse [TK] |

## ▪ METHYLPHENIDATE

**Note** Where an increase in maximum quantity is sought, under no circumstances will a quantity beyond 2 times the listed quantity be approved.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**methylphenidate hydrochloride 10 mg tablet, 100**

8839F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 27.31 | 28.71 | [a] Artige [NM] |
| | | [B]3.76 | 31.07 | 28.71 | [a] Ritalin 10 [NV] |

## ▪ METHYLPHENIDATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

**methylphenidate hydrochloride 36 mg modified release tablet, 30**

2388Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 58.93 | 30.00 | [a] Concerta [JC] | [a] METHYLPHENIDATE-TEVA XR [TB] |
| | | | | | [a] Methylphenidate XR ARX [XT] | |

## ▪ METHYLPHENIDATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

**methylphenidate hydrochloride 18 mg modified release tablet, 30**

2387P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 51.59 | 30.00 | [a] Concerta [JC] | [a] METHYLPHENIDATE-TEVA XR [TB] |
| | | | | | [a] Methylphenidate XR ARX [XT] | |

**methylphenidate hydrochloride 27 mg modified release tablet, 30**

2172H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 55.25 | 30.00 | [a] Concerta [JC] | [a] METHYLPHENIDATE-TEVA XR [TB] |
| | | | | | [a] Methylphenidate XR ARX [XT] | |

**methylphenidate hydrochloride 54 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2432B NP | 1 | 5 | .. | 67.04 | 30.00 | [a] Concerta [JC]<br>[a] Methylphenidate XR ARX [XT] | [a] METHYLPHENIDATE-TEVA XR [TB] |

## ▪ METHYLPHENIDATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**methylphenidate hydrochloride 40 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2283E NP | 1 | 5 | .. | 54.47 | 30.00 | [a] Ritalin LA [NV] | [a] Rubifen LA [AE] |

## ▪ METHYLPHENIDATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR

- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**methylphenidate hydrochloride 10 mg modified release capsule, 30**

3440C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 37.38 | 30.00 | [a] Ritalin LA [NV] | [a] Rubifen LA [AE] |

**methylphenidate hydrochloride 20 mg modified release capsule, 30**

2276T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 45.61 | 30.00 | [a] Ritalin LA [NV] | [a] Rubifen LA [AE] |

**methylphenidate hydrochloride 30 mg modified release capsule, 30**

2280B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 52.21 | 30.00 | [a] Ritalin LA [NV] | [a] Rubifen LA [AE] |

**methylphenidate hydrochloride 60 mg modified release capsule, 30**

12116Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 66.80 | 30.00 | [a] Ritalin LA [NV] | [a] Rubifen LA [AE] |

## ▪ MODAFINIL

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Narcolepsy

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with armodafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**modafinil 100 mg tablet, 60**

8816B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *170.85 | 30.00 | [a] APO-Modafinil [TX] | [a] Modafin [RW] |
| | | | | | [a] Modafinil GH [GQ] | [a] Modafinil Mylan [AF] |
| | | | | | [a] Modafinil Sandoz [SZ] | |
| | | [B]14.00 | *184.85 | 30.00 | [a] Modavigil [TB] | |

## ANTI-DEMENTIA DRUGS

*Anticholinesterases*

### ▪ DONEPEZIL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**donepezil hydrochloride 10 mg tablet, 28**

| 2479L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.99 | 22.39 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 10 [RW] | [a] Aridon APN 10 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] NOUMED DONEPEZIL [VO] | |
| | | | [B]7.15 | 28.14 | 22.39 | [a] Aricept [PF] | |

**donepezil hydrochloride 5 mg tablet, 28**

| 2532G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | .. | 20.99 | 22.39 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 5 [RW] | [a] Aridon APN 5 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] NOUMED DONEPEZIL [VO] | |
| | | | [B]2.92 | 23.91 | 22.39 | [a] Aricept [PF] | |

## ▪ DONEPEZIL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**donepezil hydrochloride 10 mg tablet, 28**

| 8496E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 20.99 | 22.39 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 10 [RW] | [a] Aridon APN 10 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] NOUMED DONEPEZIL [VO] | |
| | | | [B]7.15 | 28.14 | 22.39 | [a] Aricept [PF] | |

**donepezil hydrochloride 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8495D | 1 | 5 | .. | 20.99 | 22.39 | [a] APO-Donepezil [TX]<br>[a] Aridon 5 [RW]<br>[a] Donepezil GH [HQ]<br>[a] NOUMED DONEPEZIL [VO] | [a] Arazil [AF]<br>[a] Aridon APN 5 [RF]<br>[a] Donepezil Sandoz [SZ] |
| | | | [B]2.92 | 23.91 | 22.39 | [a] Aricept [PF] | |

## ▪ GALANTAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 16 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2537M NP | 1 | 5 | .. | 39.75 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

**galantamine 24 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2531F NP | 1 | 5 | .. | 44.88 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

**galantamine 8 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2463P NP | 1 | 5 | .. | 34.87 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

## ▪ GALANTAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**

- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**galantamine 16 mg modified release capsule, 28**

8771P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 39.75 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

**galantamine 24 mg modified release capsule, 28**

8772Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 44.88 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

**galantamine 8 mg modified release capsule, 28**

8770N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 34.87 | 30.00 | [a] APO-Galantamine MR [TX]<br>[a] Gamine XR [RW] | [a] Galantyl [AF]<br>[a] Reminyl [JC] |

## ▪ RIVASTIGMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**rivastigmine 13.3 mg/24 hours patch, 30**

10538P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 15 [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

2551G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 10 [NV] |

**rivastigmine 4.6 mg/24 hours patch, 30**

2477J

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 5 [NV] |

**rivastigmine 1.5 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2475G NP | 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 3 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2493F NP | 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2494G NP | 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 6 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2526Y NP | 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

## ▪ RIVASTIGMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**rivastigmine 13.3 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10541T | 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 15 [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9162F | 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 10 [NV] |

**rivastigmine 4.6 mg/24 hours patch, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9161E | 1 | 5 | .. | 82.49 | 30.00 | Exelon Patch 5 [NV] |

**rivastigmine 1.5 mg capsule, 56**

8497F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 3 mg capsule, 56**

8498G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

8499H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

**rivastigmine 6 mg capsule, 56**

8500J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 64.35 | 30.00 | Exelon [NV] |

*Other anti-dementia drugs*

## ▪ MEMANTINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***13966***

Moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**memantine hydrochloride 10 mg tablet, 56**

2492E

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.19 | 30.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU]<br>[a] Memanxa [RW] |

**memantine hydrochloride 20 mg tablet, 28**

2513G

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.19 | 30.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU] |

## ▪ MEMANTINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**memantine hydrochloride 10 mg tablet, 56**

1956Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.19 | 30.00 | [a] APO-Memantine [TX] | [a] Ebixa [LU] |
| | | | | | [a] Memantine generichealth [GQ] | [a] Memanxa [RW] |

**memantine hydrochloride 20 mg tablet, 28**

9306T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 43.19 | 30.00 | [a] APO-Memantine [TX] | [a] Ebixa [LU] |
| | | | | | [a] Memantine generichealth [GQ] | |

## ▪ OTHER NERVOUS SYSTEM DRUGS

### PARASYMPATHOMIMETICS

*Anticholinesterases*

### ▪ PYRIDOSTIGMINE

**pyridostigmine bromide 10 mg tablet, 50**

2724J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *25.89 | 27.29 | Mestinon [IL] |

**pyridostigmine bromide 60 mg tablet, 150**

1959D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 50.27 | 30.00 | Mestinon [IL] |

### ▪ PYRIDOSTIGMINE

**Note** Pharmaceutical benefits that have the form pyridostigmine bromide 180 mg modified release tablet in a pack size of 50 can be substituted for a pack size of 30 in the case of a shortage.

**pyridostigmine bromide 180 mg modified release tablet, 30**

13158M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3.33 | 5 | .. | *513.53 | 30.00 | [a] Pyridostigmine Bromide Extended-Release Tablets (Rising) [DZ] |

**pyridostigmine bromide 180 mg modified release tablet, 50**

2608G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *95.01 | 30.00 | [a] Mestinon Timespan [IL] |

*Choline esters*

### ▪ BETHANECHOL

**bethanechol chloride 10 mg tablet, 100**

1062X

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 30.83 | 30.00 | Uro-Carb [YN] |

### DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in nicotine dependence*

### ▪ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6881***

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**bupropion hydrochloride 150 mg modified release tablet, 90**

8710K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 170.02 | 30.00 | Zyban [AS] |

## ▪ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6882***

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**bupropion hydrochloride 150 mg modified release tablet, 30**

8465M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 64.43 | 30.00 | Zyban [AS] |

## ▪ NICOTINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**nicotine 25 mg/16 hours patch, 28**

10076H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | nicorette 16hr Invisipatch [JT] |

**nicotine 7 mg/24 hours patch, 28**

5573H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | Nicotinell Step 3 [ON] |

NP

**nicotine 14 mg/24 hours patch, 28**

5572G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | Nicotinell Step 2 [ON] |

NP

**nicotine 21 mg/24 hours patch, 28**

3414Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | Nicotinell Step 1 [ON] |

NP

**nicotine 21 mg/24 hours patch, 28**

5465P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | Nicabate P [GJ] |

NP

## ▪ NICOTINE

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**nicotine 21 mg/24 hours patch, 28**

5571F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 50.87 | 30.00 | Nicotinell Step 1 [ON] |

NP

## ▪ VARENICLINE

**Note** Pharmaceutical Benefits that have the brand APO-varenicline (Canada) may be substituted for Pharmaceutical Benefits that have the brands Champix or VARENAPIX in the case of a shortage.

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6885***

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

12978C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 101.60 | 30.00 | [a] APO-Varenicline (Canada) [XT] |

NP

**varenicline 1 mg tablet, 56**

5469W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 78.47 | 30.00 | [a] Champix [PF] | [a] VARENAPIX [TX] |

NP

## ▪ VARENICLINE

**Note** Pharmaceutical Benefits that have the brand APO-varenicline (Canada) may be substituted for Pharmaceutical Benefits that have the brands Champix or VARENAPIX in the case of a shortage.

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***7483***

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received treatment with this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

12947K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *194.07 | 30.00 | [a] APO-Varenicline (Canada) [XT] |

**varenicline 1 mg tablet, 56**

9129L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *145.49 | 30.00 | [a] Champix [PF] | [a] VARENAPIX [TX] |

## ▪ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.
**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6871***

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**varenicline 500 microgram tablet, 56**

13341E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *145.49 | 30.00 | APO-Varenicline (Canada) [XT] |

**varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53**

9128K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 68.53 | 30.00 | Champix [PF] |

*Drugs used in alcohol dependence*

## ▪ ACAMPROSATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***5366***

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**acamprosate calcium 333 mg enteric tablet, 180**

8357W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 78.78 | 30.00 | [a] Acamprosate Mylan [AL] | [a] ACAMPROSATE VIATRIS [MQ] |
| | | | | | [a] APO-Acamprosate [TX] | [a] Campral [AF] |

NP

## ▪ NALTREXONE

**Caution** Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***13967***

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.

**naltrexone hydrochloride 50 mg tablet, 30**

8370M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 104.96 | 30.00 | Naltrexone GH [GQ] |

NP

# OTHER NERVOUS SYSTEM DRUGS

*Other nervous system drugs*

## ▪ AMIFAMPRIDINE

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Lambert-Eaton myasthenic syndrome (LEMS)

**Clinical criteria:**

- The condition must not be any of: (i) myasthenia gravis, (ii) Guillain-Barre syndrome.

**Treatment criteria:**

- Must be treated by a prescriber type identifying as at least one of the following: (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists.

**amifampridine 10 mg tablet, 100**

13032X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *4460.91 | 30.00 | Ruzurgi [OJ] |

## ▪ RILUZOLE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**

- Patient must not have experienced respiratory failure.

**riluzole 50 mg/10 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11662T NP | 2 | 5 | .. | *245.37 | 30.00 | Teglutik [CS] |

**riluzole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8664B NP | 1 | 5 | .. | 175.15 | 30.00 | [a] APO-Riluzole [TX]<br>[a] Rilutek [SW] | [a] Pharmacor Riluzole [CR]<br>[a] Riluzole Sandoz [SZ] |

## ▪ TETRABENAZINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5340***

Hyperkinetic extrapyramidal disorders

**tetrabenazine 25 mg tablet, 112**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1330B NP | 1 | 5 | .. | 236.01 | 30.00 | [a] iNova Pharmaceuticals (Australia) Pty Ltd [IL] | [a] Tetrabenazine SUN [RA] |

# ▪ ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

# ▪ ANTIPROTOZOALS

## AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

*Other agents against amoebiasis and other protozoal diseases*

## ▪ ATOVAQUONE

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5609***

Mild to moderate Pneumocystis carinii pneumonia

**Population criteria:**

- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8300W NP | ‡1 | .. | .. | 982.01 | 30.00 | Wellvone [AS] |

## ANTIMALARIALS

*Biguanides*

## ▪ ATOVAQUONE + PROGUANIL

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**Population criteria:**

- Patient must be aged 3 years or older.

**Clinical criteria:**

- The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9439T NP | 1 | .. | .. | 68.06 | 30.00 | [a] AtovaquoPro Lupin 250/100 [GQ] | [a] Malarone [GK] |

*Methanolquinolines*

### ▪ QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.

**Authority required (STREAMLINED)**

***5633***

Malaria

**quinine sulfate dihydrate 300 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1975Y | 1 | 2 | .. | 21.81 | 23.21 | Quinate [RW] |

NP

*Artemisinin and derivatives, combinations*

### ▪ ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**Clinical criteria:**

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

**artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5296R | 1 | .. | .. | 101.45 | 30.00 | Riamet 20mg/120mg Dispersible [SZ] |

### ▪ ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**artemether 20 mg + lumefantrine 120 mg tablet, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9498X | 1 | .. | .. | 83.32 | 30.00 | Riamet [SZ] |

## ▪ ANTHELMINTICS

### ANTITREMATODALS

*Quinoline derivatives and related substances*

### ▪ PRAZIQUANTEL

**Authority required (STREAMLINED)**

***5659***

Schistosomiasis

**praziquantel 600 mg tablet, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9447F | 1 | .. | .. | 38.59 | 30.00 | Biltricide [BN] |

NP

### ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

### ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**

***5607***

Hydatid disease

**Clinical criteria:**

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

**albendazole 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8459F | 1 | 2 | .. | 115.84 | 30.00 | Eskazole [AS] |

### ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**

***5680***

Tapeworm infestation

**albendazole 200 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8503M NP | 1 | 1 | .. | 28.72 | 30.00 | Zentel [AS] |

## ▪ ALBENDAZOLE

**Authority required (STREAMLINED)**

***5817***

Whipworm infestation

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

***5712***

Strongyloidiasis

**Authority required (STREAMLINED)**

***5797***

Hookworm infestation

**albendazole 200 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9047E NP | 1 | .. | .. | 28.72 | 30.00 | Zentel [AS] |

*Tetrahydropyrimidine derivatives*

## ▪ PYRANTEL

**pyrantel 125 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3047J NP | 1 | .. | .. | 17.58 | 18.98 | Anthel 125 [AF] |

**pyrantel 250 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3048K NP | 1 | .. | .. | 21.98 | 23.38 | Anthel 250 [AF] |

*Avermectines*

## ▪ IVERMECTIN

**Authority required (STREAMLINED)**

***4319***

Onchocerciasis

**ivermectin 3 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8359Y NP | 1 | .. | .. | 30.57 | 30.00 | Stromectol [MK] |

## ▪ IVERMECTIN

**Authority required (STREAMLINED)**

***4328***

Strongyloidiasis

**Authority required (STREAMLINED)**

***4565***

Crusted (Norwegian) scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Authority required (STREAMLINED)**

***4566***

Human sarcoptic scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.

**Authority required (STREAMLINED)**

***12604***

Human sarcoptic scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander, **AND**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**ivermectin 3 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2868Y NP | 2 | 2 | .. | *48.15 | 30.00 | Stromectol [MK] |

# ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

## ECTOPARASITICIDES, INCL. SCABICIDES

*Pyrethrines, incl. synthetic compounds*

### PERMETHRIN

**permethrin 5% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3054R NP | ‡1 | 1 | .. | 20.31 | 21.71 | Lyclear [JT] |

# RESPIRATORY SYSTEM

# NASAL PREPARATIONS

## DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Other nasal preparations*

### MUPIROCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6647***

Staphylococcus aureus infection

**Clinical criteria:**

- Patient must have nasal colonisation with the bacteria.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**mupirocin 2% ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11822F NP | ‡1 | .. | .. | 26.51 | 27.91 | Mupirocin Nasal (Medsurge) [DZ] |

**mupirocin 2% ointment, 3 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9440W NP | ‡1 | .. | .. | 26.51 | 27.91 | Bactroban [GK] |

# DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

## ADRENERGICS, INHALANTS

*Selective beta-2-adrenoreceptor agonists*

### FORMOTEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8136F NP | 1 | 5 | .. | 29.98 | 30.00 | Foradile [SZ] |

**formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

8240Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 29.48 | 30.00 | Oxis Turbuhaler [AP] |

**formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

8239P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 23.96 | 25.36 | Oxis Turbuhaler [AP] |

## ▪ INDACATEROL

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**indacaterol 150 microgram powder for inhalation, 30 capsules**

5134F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.90 | 30.00 | Onbrez [NV] |

**indacaterol 300 microgram powder for inhalation, 30 capsules**

5137J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 58.90 | 30.00 | Onbrez [NV] |

## ▪ SALBUTAMOL

**salbutamol 100 microgram/actuation inhalation, 200 actuations**

12109H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *23.57 | 24.97 | [a] Zempreon CFC-Free with dose counter [AL] |
| | | [B]2.00 | *25.57 | 24.97 | [a] Asmol CFC-Free with dose counter [AF] |
| | | [B]5.02 | *28.59 | 24.97 | [a] Ventolin CFC-Free with dose counter [GK] |

## ▪ SALBUTAMOL

**Restricted benefit**

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations**

8354Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *40.97 | 30.00 | Airomir Autohaler [IL] |

## ▪ SALBUTAMOL

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution**.**

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

11130T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | [B]5.04 | *27.63 | 23.99 | [a] Ventolin Nebules [GK] |

**salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11095Y NP | 3 | 5 | [B]5.01 | *28.02 | 24.41 | [a] Ventolin Nebules [GK] |

**salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2000G NP | 2 | 5 | .. | *20.99 | 22.39 | [a] Salbutamol Cipla [LR] |

**salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2001H NP | 2 | 5 | .. | *21.41 | 22.81 | [a] Salbutamol AN [ED] | [a] Salbutamol Cipla [LR] |

## ▪ SALMETEROL

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8141L NP | ‡1 | 5 | .. | 29.98 | 30.00 | Serevent Accuhaler [GK] |

## ▪ TERBUTALINE

**Authority required (STREAMLINED)**

***9828***

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; OR
- Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12267P NP | 2 | 5 | .. | *27.65 | 29.05 | Bricanyl Turbuhaler [AP] |

*Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics*

## ▪ BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority required (STREAMLINED)**

***11057***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12183F NP | ‡1 | 5 | .. | 37.82 | 30.00 | Fostair [EU] |

## ▪ BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority required (STREAMLINED)**

***11057***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

13205B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 47.53 | 30.00 | Fostair 200/6 [EU] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

***10482***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

**Population criteria:**

- Patient must be aged 12 years or over.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12042T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 2 | .. | *41.81 | 30.00 | [a] Rilast RAPIHALER 100/3 [ZA] | [a] Symbicort Rapihaler 100/3 [AP] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

***10464***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12029D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 2 | .. | 37.00 | 30.00 | [a] BiResp Spiromax [TB] | [a] DuoResp Spiromax [EV] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

***10464***
Mild asthma
**Clinical criteria:**
- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12041R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 2 | .. | 37.00 | 30.00 | [a] Rilast TURBUHALER 200/6 [ZA] | [a] Symbicort Turbuhaler 200/6 [AP] |

NP

## ▪ BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma
**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**
***4380***
Asthma
**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**
- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8796Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 40.50 | 30.00 | Symbicort Turbuhaler 100/6 [AP] |

NP

## ▪ BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma
**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**
***4397***
Asthma
**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**
- Patient must be aged 12 years or over.

**budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

10024N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *40.49 | 30.00 | Symbicort Rapihaler 50/3 [AP] |

NP

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

10015D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *41.81 | 30.00 | [a] Rilast RAPIHALER 100/3 [ZA] | [a] Symbicort Rapihaler 100/3 [AP] |

NP

## ▪ BUDESONIDE + FORMOTEROL

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***10538***

Asthma

**Clinical criteria:**

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

12082X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | .. | *60.43 | 30.00 | [a] Rilast RAPIHALER 200/6 [ZA] | [a] Symbicort Rapihaler 200/6 [AP] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***10538***

Asthma

**Clinical criteria:**

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12100W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | .. | *40.49 | 30.00 | Symbicort Rapihaler 50/3 [AP] |

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12089G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | .. | *41.81 | 30.00 | [a] Rilast RAPIHALER 100/3 [ZA] | [a] Symbicort Rapihaler 100/3 [AP] |

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12101X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 40.50 | 30.00 | Symbicort Turbuhaler 100/6 [AP] |

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12093L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 37.00 | 30.00 | [a] BiResp Spiromax [TB]<br>[a] Rilast TURBUHALER 200/6 [ZA] | [a] DuoResp Spiromax [EV]<br>[a] Symbicort Turbuhaler 200/6 [AP] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma
**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**
***7970***
Asthma
**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

11273H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 37.00 | 30.00 | [a] BiResp Spiromax [TB] | [a] DuoResp Spiromax [EV] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.
**Note** Patient must be aged 12 years or over.
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**
***7970***
Asthma
**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8625Y (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 37.00 | 30.00 | [a] Rilast TURBUHALER 200/6 [ZA] | [a] Symbicort Turbuhaler 200/6 [AP] |

## ▪ BUDESONIDE + FORMOTEROL

**Authority required (STREAMLINED)**
***4404***
Asthma
**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**
***10121***
Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

10018G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *60.43 | 30.00 | [a] Rilast RAPIHALER 200/6 [ZA] | [a] Symbicort Rapihaler 200/6 [AP] |

## ▪ BUDESONIDE + FORMOTEROL

**Note** For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

**Note** Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

**Authority required (STREAMLINED)**

***7979***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** Patient must be aged 18 years or older.

**Note** Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

13258T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *60.45 | 30.00 | [a] DuoResp Spiromax [EV] | [a] Rilast TURBUHALER 400/12 [ZA] |
| | | [B]4.00 | *64.45 | 30.00 | [a] Symbicort TURBUHALER 400/12 [AP] | |

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations**

11301T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 60.45 | 30.00 | [a] BiResp Spiromax [TB] | [a] DuoResp Spiromax [EV] |

## ▪ FLUTICASONE FUROATE + VILANTEROL

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***4731***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11129R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 73.52 | 30.00 | Breo Ellipta 200/25 [GK] |

NP

## ▪ FLUTICASONE FUROATE + VILANTEROL

**Authority required (STREAMLINED)**

***4711***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11124L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 58.02 | 30.00 | Breo Ellipta 100/25 [GK] |

NP

## ▪ FLUTICASONE PROPIONATE + FORMOTEROL

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***4395***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

2827T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 38.81 | 30.00 | flutiform 50/5 [MF] |

**fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

10007Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 39.38 | 30.00 | flutiform 125/5 [MF] |

**fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations**

10008R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 51.10 | 30.00 | flutiform 250/10 [MF] |

## ▪ FLUTICASONE PROPIONATE + SALMETEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***4930***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

8518H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 45.78 | 30.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 125/25 [LR] |
| | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 125/25 [SZ] |
| | | | | | [a] Seroflo 125/25 [YC] | |
| | | [B]3.53 | 49.31 | 30.00 | [a] Seretide MDI 125/25 [GK] | |

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

8517G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.46 | 30.00 | [a] PAVTIDE MDI 50/25 [TX] |
| | | [B]4.00 | 47.46 | 30.00 | [a] Seretide MDI 50/25 [GK] |

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8430Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.46 | 30.00 | [a] PAVTIDE ACCUHALER 100/50 [TX] |
| | | [B]4.00 | 47.46 | 30.00 | [a] Seretide Accuhaler 100/50 [GK] |

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8431R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 45.78 | 30.00 | [a] Fluticasone Salmeterol Ciphaler 250/50 [LR] | [a] PAVTIDE ACCUHALER 250/50 [TX] |
| | | [B]3.53 | 49.31 | 30.00 | [a] Seretide Accuhaler 250/50 [GK] | |

## ▪ FLUTICASONE PROPIONATE + SALMETEROL

**Authority required (STREAMLINED)**

***4930***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.
**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8519J NP | ‡1 | 5 | .. | 57.39 | 30.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 250/25 [LR] |
| | | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 250/25 [SZ] |
| | | | | | | [a] Seroflo 250/25 [YC] | |
| | | | [B]3.52 | 60.91 | 30.00 | [a] Seretide MDI 250/25 [GK] | |

**fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8432T NP | ‡1 | 5 | .. | 57.39 | 30.00 | [a] Fluticasone Salmeterol Ciphaler 500/50 [LR] | [a] PAVTIDE ACCUHALER 500/50 [TX] |
| | | | [B]3.52 | 60.91 | 30.00 | [a] Seretide Accuhaler 500/50 [GK] | |

## ▪ INDACATEROL + MOMETASONE

**Note** This product is not indicated for the initiation of treatment in asthma
**Note** This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***11360***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12269R NP | 1 | 5 | .. | 37.50 | 30.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12279G NP | 1 | 5 | .. | 59.14 | 30.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12289T NP | 1 | 5 | .. | 43.31 | 30.00 | Atectura Breezhaler [NV] |

*Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids*

## ▪ ACLIDINIUM + FORMOTEROL

**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

10565C NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 81.78 | 30.00 | Brimica Genuair [FK] |

## ▪ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***12349***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

12468F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 81.28 | 30.00 | Trimbow [EU] |

## ▪ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

***12603***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

13200R NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 79.46 | 30.00 | Trimbow [EU] |

## ▪ BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***12349***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

12672Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 80.35 | 30.00 | Breztri Aerosphere [AP] |

## ▪ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***12349***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11379X NP | ‡1 | 5 | .. | 89.01 | 30.00 | Trelegy Ellipta 100/62.5/25 [GK] |

## ▪ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

***12603***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12917W NP | ‡1 | 5 | .. | 92.57 | 30.00 | Trelegy Ellipta 200/62.5/25 [GK] |

## ▪ INDACATEROL + GLYCOPYRRONIUM

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10156M NP | 1 | 5 | .. | 88.76 | 30.00 | ultibro breezhaler 110/50 [NV] |

## ▪ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

***12603***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules**

12295D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 90.76 | 30.00 | Enerzair Breezhaler [NV] |

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules**

12298G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 74.47 | 30.00 | Enerzair Breezhaler [NV] |

## ▪ TIOTROPIUM + OLODATEROL

**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** A SAMA includes ipratropium
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

10557P (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 74.57 | 30.00 | Spiolto Respimat [BY] |

## ▪ UMECLIDINIUM + VILANTEROL

**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** A SAMA includes ipratropium
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10188F NP | ‡1 | 5 | .. | 90.38 | 30.00 | Anoro Ellipta 62.5/25 [GK] |

## OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

*Glucocorticoids*

### ▪ BECLOMETASONE

**beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8406K NP | ‡1 | 5 | .. | 20.06 | 21.46 | Qvar 50 [IL] |

**beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8407L NP | ‡1 | 5 | .. | 27.85 | 29.25 | Qvar 100 [IL] |

### ▪ BECLOMETASONE

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8409N NP | ‡1 | 5 | .. | 30.96 | 30.00 | Qvar 100 Autohaler [IL] |

**beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8408M NP | ‡1 | 5 | .. | 24.77 | 26.17 | Qvar 50 Autohaler [IL] |

### ▪ BUDESONIDE

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2070Y NP | ‡1 | 5 | .. | 22.29 | 23.69 | Pulmicort Turbuhaler [AP] |

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2071B NP | ‡1 | 5 | .. | 26.53 | 27.93 | Pulmicort Turbuhaler [AP] |

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2072C NP | ‡1 | 5 | .. | 35.06 | 30.00 | Pulmicort Turbuhaler [AP] |

### ▪ BUDESONIDE

**Authority required (STREAMLINED)**

***6340***

Severe chronic asthma

**Clinical criteria:**

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2066R NP | ‡1 | 5 | .. | 37.05 | 30.00 | Pulmicort Respules [AP] |

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2065Q NP | ‡1 | 5 | .. | 30.27 | 30.00 | Pulmicort Respules [AP] |

## ▪ CICLESONIDE

### ciclesonide 160 microgram/actuation inhalation, 120 actuations

8854B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 32.77 | 30.00 | Alvesco 160 [EU] |

### ciclesonide 80 microgram/actuation inhalation, 120 actuations

8853Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 23.83 | 25.23 | Alvesco 80 [EU] |

## ▪ FLUTICASONE FUROATE

### fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations

11719T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 29.82 | 30.00 | Arnuity Ellipta [GK] |

### fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations

11729H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.96 | 30.00 | Arnuity Ellipta [GK] |

## ▪ FLUTICASONE PROPIONATE

### fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

8345F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 26.31 | 27.71 | [a] Axotide [TX] | [a] Fluticasone Cipla Inhaler [LR] |
| | | [B]2.38 | 28.69 | 27.71 | [a] Flixotide [GK] | |

### fluticasone propionate 250 microgram/actuation inhalation, 120 actuations

8346G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 1 | .. | 37.50 | 30.00 | [a] Axotide [TX] | [a] Fluticasone Cipla Inhaler [LR] |
| | | [B]2.38 | 39.88 | 30.00 | [a] Flixotide [GK] | |

### fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

8147T NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.85 | 20.25 | [a] Axotide Junior Accuhaler [TX] |
| | | [B]3.17 | 22.02 | 20.25 | [a] Flixotide Junior Accuhaler [GK] |

### fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

8148W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 26.31 | 27.71 | [a] Axotide Accuhaler [TX] |
| | | [B]3.17 | 29.48 | 27.71 | [a] Flixotide Accuhaler [GK] |

### fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations

8149X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 37.50 | 30.00 | Flixotide Accuhaler [GK] |

## ▪ FLUTICASONE PROPIONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***14180***

Asthma

**Clinical criteria:**

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.

### fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

8516F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 20.40 | 21.80 | [a] Axotide Junior [TX] |
| | | [B]4.00 | 24.40 | 21.80 | [a] Flixotide Junior [GK] |

*Anticholinergics*

## ▪ ACLIDINIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations**

10124W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 61.32 | 30.00 | Bretaris Genuair [FK] |

NP

## ▪ GLYCOPYRRONIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

10059K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 61.32 | 30.00 | seebri breezhaler [NV] |

NP

## ▪ IPRATROPIUM

**ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations**

8671J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *34.13 | 30.00 | Atrovent [BY] |

NP

## ▪ IPRATROPIUM

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules**

1542E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *29.23 | 30.00 | [a] Aeron 250 [AL]<br>[a] Ipratrin [AF] | [a] APO-Ipratropium [TX] |
| | | [B]0.50 | *29.73 | 30.00 | [a] Atrovent [BY] | |

NP

**ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules**

8238N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | .. | *32.17 | 30.00 | [a] Aeron 500 [AL]<br>[a] Ipratrin Adult [AF] | [a] APO-Ipratropium [TX] |
| | | [B]0.50 | *32.67 | 30.00 | [a] Atrovent Adult [BY] | |

NP

## ▪ TIOTROPIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Restricted benefit**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique,

**AND**

- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

11043F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.98 | 30.00 | Spiriva Respimat [BY] |

NP

## ▪ TIOTROPIUM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

***8606***

Severe asthma

**Treatment criteria:**

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

11629C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.98 | 30.00 | Spiriva Respimat [BY] |

NP

## ▪ TIOTROPIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

10509D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 43.98 | 30.00 | Spiriva Respimat [BY] |

NP

## ▪ TIOTROPIUM

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**tiotropium 13 microgram powder for inhalation, 30 capsules**

11892X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 39.10 | 30.00 | [a] Braltus [TB] |

**tiotropium 18 microgram powder for inhalation, 30 capsules**

8626B NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 43.98 | 30.00 | [a] Spiriva [BY] |

## ▪ UMECLIDINIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations**

10187E NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 61.32 | 30.00 | Incruse Ellipta [GK] |

# ADRENERGICS FOR SYSTEMIC USE

*Alpha- and beta-adrenoreceptor agonists*

## ▪ ADRENALINE (EPINEPHRINE)

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

1016L NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 20.63 | 22.03 | Link Medical Products Pty Ltd [LM] |

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

5004J DP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 20.63 | 22.03 | Link Medical Products Pty Ltd [LM] |

## ▪ ADRENALINE (EPINEPHRINE)

**Caution** Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12655C NP | 2 | .. | .. | *159.69 | 30.00 | Anapen 500 [XT] |

**adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8697R NP | 2 | .. | .. | *159.69 | 30.00 | [a] Adrenaline Jr Viatris [AF]<br>[a] EpiPen Jr. [AL] | [a] Anapen Junior 150 [XT] |

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8698T NP | 2 | .. | .. | *159.69 | 30.00 | [a] Adrenaline Viatris [AF]<br>[a] EpiPen [AL] | [a] Anapen 300 [XT] |

*Selective beta-2-adrenoreceptor agonists*

## ▪ SALBUTAMOL

**salbutamol 2 mg/5 mL oral liquid, 150 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1103C NP | 2 | 5 | .. | *26.71 | 28.11 | Ventolin [GK] |

## ▪ TERBUTALINE

**terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1034K NP | 1 | .. | .. | 26.27 | 27.67 | Bricanyl [AP] |

# OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Xanthines*

## ▪ THEOPHYLLINE

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**theophylline 133.3 mg/25 mL oral liquid, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2614N NP | ‡1 | 5 | .. | 17.85 | 19.25 | Nuelin [IL] |

**theophylline 200 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8230E NP | 1 | 5 | .. | 17.55 | 18.95 | Nuelin-SR 200 [IL] |

**theophylline 250 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2634P NP | 1 | 5 | .. | 18.38 | 19.78 | Nuelin-SR 250 [IL] |

**theophylline 300 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8231F NP | 1 | 5 | .. | 19.44 | 20.84 | Nuelin-SR 300 [IL] |

*Leukotriene receptor antagonists*

## ▪ MONTELUKAST

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6666***

Asthma

Treatment Phase: First-line prevention

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**montelukast 4 mg chewable tablet, 28**

8627C

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.89 | 20.29 | [a] MONTELAIR 4 [RF]<br>[a] Montelukast Lupin [HQ]<br>[a] Montelukast Sandoz 4 [SZ] | [a] Montelukast APOTEX [GX]<br>[a] Montelukast Mylan [AF] |

## ▪ MONTELUKAST

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6674***

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Authority required (STREAMLINED)**

***7781***

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**montelukast 5 mg chewable tablet, 28**

8628D

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.57 | 19.97 | [a] MONTELAIR 5 [RF]<br>[a] Montelukast Lupin [HQ]<br>[a] Montelukast Sandoz 5 [SZ] | [a] Montelukast APOTEX [GX]<br>[a] Montelukast Mylan [AF] |

# ▪ ANTIHISTAMINES FOR SYSTEMIC USE

## ANTIHISTAMINES FOR SYSTEMIC USE

*Phenothiazine derivatives*

### ▪ PROMETHAZINE

**promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1948M NP | 2 | .. | .. | *31.33 | 30.00 | DBL Promethazine Hydrochloride [PF] |

# ▪ SENSORY ORGANS

## ▪ OPHTHALMOLOGICALS

### ANTIINFECTIVES

*Antibiotics*

### ▪ AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Trachoma

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8201P NP | ‡1 | .. | .. | #28.49 | 30.00 | Zithromax [PF] |

**azithromycin 500 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8336R NP | 1 | 2 | .. | 17.38 | 18.78 | [a] APO-Azithromycin [TX]<br>[a] Azithromycin Sandoz [SZ]<br>[a] Zithromax [PF] | [a] Azithromycin Mylan [AF]<br>[a] ZITHRO [RW] |

### ▪ CHLORAMPHENICOL

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**chloramphenicol 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11112W OP NP MW | ‡1 | 2 | .. | 17.10 | 18.50 | Chlorsig [AS] |

### ▪ TOBRAMYCIN

**Restricted benefit**
Perioperative use in ophthalmic surgery
**Restricted benefit**
Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5569D OP | ‡1 | 2 | .. | 23.61 | 25.01 | Tobrex [NV] |

**tobramycin 0.3% eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5570E OP | ‡1 | .. | .. | 26.17 | 27.57 | Tobrex [NV] |

### ▪ TOBRAMYCIN

**Restricted benefit**
Invasive ocular infection
**Restricted benefit**
Perioperative use in ophthalmic surgery
**Restricted benefit**
Suspected Pseudomonal eye infection

**tobramycin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2328M | ‡1 | 2 | .. | 23.61 | 25.01 | Tobrex [NV] |

**tobramycin 0.3% eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2329N | ‡1 | .. | .. | 26.17 | 27.57 | Tobrex [NV] |

*Antivirals*

## ▪ ACICLOVIR

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

5501M (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | .. | .. | 32.01 | 30.00 | [a] ViruPOS [AE] | [a] XOROX [IX] |

## ▪ ACICLOVIR

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

1002R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | .. | .. | 32.01 | 30.00 | [a] ViruPOS [AE] | [a] XOROX [IX] |

*Fluoroquinolones*

## ▪ CIPROFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

1217C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *32.17 | 30.00 | [a] CiloQuin [NM] |
| | | [B]4.36 | *36.53 | 30.00 | [a] Ciloxan [NV] |

## ▪ CIPROFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

5564W (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *32.17 | 30.00 | [a] CiloQuin [NM] |
| | | [B]4.36 | *36.53 | 30.00 | [a] Ciloxan [NV] |

## ▪ OFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

5567B (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *28.85 | 30.00 | Ocuflox [VE] |

## ▪ OFLOXACIN

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

8383F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *28.85 | 30.00 | Ocuflox [VE] |

# ANTIINFLAMMATORY AGENTS

*Corticosteroids, plain*

## ▪ DEXAMETHASONE

### dexamethasone 0.1% eye drops, 5 mL

1288T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 23.12 | 24.52 | Maxidex [NV] |

NP

## ▪ DEXAMETHASONE

**Authority required**

Non-infectious posterior segment uveitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

### dexamethasone 700 microgram implant, 1

11317P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 1211.27 | 30.00 | Ozurdex [VE] |

## ▪ DEXAMETHASONE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

### dexamethasone 0.1% eye drops, 5 mL

5565X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 23.12 | 24.52 | Maxidex [NV] |

OP

## ▪ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**dexamethasone 700 microgram implant, 1**

10943Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1211.27 | 30.00 | Ozurdex [VE] |

## ▪ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13428***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**dexamethasone 700 microgram implant, 1**

13168C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1211.27 | 30.00 | Ozurdex [VE] |

## ▪ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**dexamethasone 700 microgram implant, 1**

11469P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1211.27 | 30.00 | Ozurdex [VE] |

## ▪ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

***13336***
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment
**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**dexamethasone 700 microgram implant, 1**

13142Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 1211.27 | 30.00 | Ozurdex [VE] |

## ▪ FLUOROMETHOLONE

**fluorometholone 0.1% eye drops, 5 mL**

1204J

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 16.15 | 17.55 | FML Liquifilm [VE] |

## ▪ FLUOROMETHOLONE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

**fluorometholone 0.1% eye drops, 5 mL**

5513E

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 16.15 | 17.55 | FML Liquifilm [VE] |

## ▪ FLUOROMETHOLONE ACETATE

**fluorometholone acetate 0.1% eye drops, 5 mL**

1438Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 16.15 | 17.55 | Flarex [NV] |

## ▪ FLUOROMETHOLONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

**fluorometholone acetate 0.1% eye drops, 5 mL**

5533F

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 16.15 | 17.55 | Flarex [NV] |

## ▪ HYDROCORTISONE ACETATE

**hydrocortisone acetate 1% eye ointment, 5 g**

2441L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.47 | 19.87 | Hycor [AS] |

## ▪ HYDROCORTISONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

**hydrocortisone acetate 1% eye ointment, 5 g**

5516H

OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.47 | 19.87 | Hycor [AS] |

*Corticosteroids and mydriatics in combination*

## ▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
Severe eye inflammation
**Clinical criteria:**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

11908R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 23.65 | 25.05 | Prednefrin Forte [VE] |

## ▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
Corneal grafts
**Restricted benefit**
Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3112T NP | ‡1 | 2 | .. | 23.65 | 25.05 | Prednefrin Forte [VE] |

## ▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5568C OP | ‡1 | .. | .. | 23.65 | 25.05 | Prednefrin Forte [VE] |

# ANTIGLAUCOMA PREPARATIONS AND MIOTICS

*Sympathomimetics in glaucoma therapy*

## ▪ BRIMONIDINE

**brimonidine tartrate 0.15% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5298W | ‡1 | 5 | .. | 20.69 | 22.09 | Alphagan P 1.5 [VE] |

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8351M | ‡1 | 5 | .. | 21.16 | 22.56 | [a] Enidin [VB] |
| | | | [B]0.98 | 22.14 | 22.56 | [a] Alphagan [VE] |

## ▪ BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brimonidine tartrate 0.15% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5563T OP | ‡1 | 5 | .. | 20.69 | 22.09 | Alphagan P 1.5 [VE] |

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5534G OP | ‡1 | 5 | .. | 21.16 | 22.56 | [a] Enidin [VB] |
| | | | [B]0.98 | 22.14 | 22.56 | [a] Alphagan [VE] |

## ▪ BRIMONIDINE + TIMOLOL

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8826M | ‡1 | 5 | .. | 25.71 | 27.11 | Combigan [VE] |

## ▪ BRIMONIDINE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5535H OP | ‡1 | 5 | .. | 25.71 | 27.11 | Combigan [VE] |

*Parasympathomimetics*

## ▪ PILOCARPINE

**pilocarpine hydrochloride 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2595N | ‡1 | 5 | .. | 18.34 | 19.74 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 2% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2596P | ‡1 | 5 | .. | 19.39 | 20.79 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2598R | ‡1 | 5 | .. | 21.87 | 23.27 | Isopto Carpine [NV] |

## ▪ PILOCARPINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**pilocarpine hydrochloride 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5536J OP | ‡1 | 5 | .. | 18.34 | 19.74 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 2% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5537K OP | ‡1 | 5 | .. | 19.39 | 20.79 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5538L OP | ‡1 | 5 | .. | 21.87 | 23.27 | Isopto Carpine [NV] |

*Carbonic anhydrase inhibitors*

## ▪ ACETAZOLAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**acetazolamide 250 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1004W NP | 1 | 3 | .. | 23.51 | 24.91 | Diamox [RW] |

## ▪ BRINZOLAMIDE

**brinzolamide 1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8483L | ‡1 | 5 | .. | 22.73 | 24.13 | [a] BrinzoQuin [NM] |
| | | | [B]3.27 | 26.00 | 24.13 | [a] Azopt [NV] |

## ▪ BRINZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5540N OP | ‡1 | 5 | .. | 22.73 | 24.13 | [a] BrinzoQuin [NM] |
| | | | [B]3.27 | 26.00 | 24.13 | [a] Azopt [NV] |

## ▪ BRINZOLAMIDE + BRIMONIDINE

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10536M | ‡1 | 5 | .. | 24.33 | 25.73 | Simbrinza 1%/0.2% [NV] |

## ▪ BRINZOLAMIDE + BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10547D (OP) | ‡1 | 5 | .. | 24.33 | 25.73 | Simbrinza 1%/0.2% [NV] |

## ▪ BRINZOLAMIDE + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3438Y | ‡1 | 5 | .. | 26.20 | 27.60 | Azarga [NV] |

## ▪ BRINZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5562R (OP) | ‡1 | 5 | .. | 26.20 | 27.60 | Azarga [NV] |

## ▪ DORZOLAMIDE

**dorzolamide 2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8488R | ‡1 | 5 | .. | 19.71 | 21.11 | [a] Trusamide [AF] | [a] Trusopt [MF] |

## ▪ DORZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5541P (OP) | ‡1 | 5 | .. | 19.71 | 21.11 | [a] Trusamide [AF] | [a] Trusopt [MF] |

## ▪ DORZOLAMIDE + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8567X | ‡1 | 5 | .. | 21.52 | 22.92 | [a] Cosdor [AF] | [a] Vizo-PF Dorzolatim [AE] |
| | | | [B]0.80 | 22.32 | 22.92 | [a] Cosopt [MF] | |

## ▪ DORZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

5542Q (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 21.52 | 22.92 | [a] Cosdor [AF] | [a] Vizo-PF Dorzolatim [AE] |
| | | [B]0.80 | 22.32 | 22.92 | [a] Cosopt [MF] | |

*Beta blocking agents*

## ▪ BETAXOLOL

**betaxolol 0.5% eye drops, 5 mL**

2825Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 20.25 | 21.65 | [a] BetoQuin [NM] |
| | | [B]4.76 | 25.01 | 21.65 | [a] Betoptic [NV] |

## ▪ BETAXOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**betaxolol 0.5% eye drops, 5 mL**

5544T (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 20.25 | 21.65 | [a] BetoQuin [NM] |
| | | [B]4.76 | 25.01 | 21.65 | [a] Betoptic [NV] |

## ▪ TIMOLOL

**timolol 0.5% eye drops, 2.5 mL**

1926J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.17 | 19.57 | Timoptol XE [MF] |

**timolol 0.5% eye drops, 5 mL**

1279H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.12 | 19.52 | Timoptol [MF] |

## ▪ TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**timolol 0.5% eye drops, 2.5 mL**

5550D (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.17 | 19.57 | Timoptol XE [MF] |

**timolol 0.5% eye drops, 5 mL**

5548B (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 18.12 | 19.52 | Timoptol [MF] |

*Prostaglandin analogues*

## ▪ BIMATOPROST

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

10046R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 29.56 | 30.00 | Lumigan PF [VE] |

**bimatoprost 0.03% eye drops, 3 mL**

8620Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 32.72 | 30.00 | [a] Bimatoprost Sandoz [SZ] | [a] Bimprozt [TY] |
| | | | | | [a] Bimtop [AF] | [a] Lumigan [VE] |

## ▪ BIMATOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

10053D (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 29.56 | 30.00 | Lumigan PF [VE] |

**bimatoprost 0.03% eye drops, 3 mL**

5551E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 32.72 | 30.00 | [a] Bimatoprost Sandoz [SZ]<br>[a] Bimtop [AF] | [a] Bimprozt [TY]<br>[a] Lumigan [VE] |

OP

## ▪ BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

10107Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.31 | 30.00 | GANfort PF 0.3/5 [VE] |

## ▪ BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

9464D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 36.58 | 30.00 | Ganfort 0.3/5 [VE] |

## ▪ BIMATOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

5558M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 36.58 | 30.00 | Ganfort 0.3/5 [VE] |

OP

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

10108B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.31 | 30.00 | GANfort PF 0.3/5 [VE] |

OP

## ▪ LATANOPROST

**latanoprost 0.005% eye drops, 2.5 mL**

8243W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 17.54 | 18.94 | [a] APO-Latanoprost [TX]<br>[a] Xalaprost [AF] | [a] Latanoprost Sandoz [SZ]<br>[a] Xalatan [AS] |

## ▪ LATANOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**latanoprost 0.005% eye drops, 2.5 mL**

5552F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 17.54 | 18.94 | [a] APO-Latanoprost [TX]<br>[a] Xalaprost [AF] | [a] Latanoprost Sandoz [SZ]<br>[a] Xalatan [AS] |

OP

## ▪ LATANOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8895E | ‡1 | 5 | .. | 21.14 | 22.54 | [a] APO-Latanoprost/Timolol 0.05/5 [TX]<br>[a] Xalamol 50/5 [AF] | [a] Xalacom [AS] |

## ▪ LATANOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5553G OP | ‡1 | 5 | .. | 21.14 | 22.54 | [a] APO-Latanoprost/Timolol 0.05/5 [TX]<br>[a] Xalamol 50/5 [AF] | [a] Xalacom [AS] |

## ▪ TAFLUPROST

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2755B | ‡1 | 5 | .. | 35.62 | 30.00 | Saflutan [MF] |

## ▪ TAFLUPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2748P OP | ‡1 | 5 | .. | 35.62 | 30.00 | Saflutan [MF] |

## ▪ TRAVOPROST

**travoprost 0.004% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8597L | ‡1 | 5 | .. | 32.72 | 30.00 | Travatan [NV] |

## ▪ TRAVOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**travoprost 0.004% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5554H OP | ‡1 | 5 | .. | 32.72 | 30.00 | Travatan [NV] |

## ▪ TRAVOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9057Q | ‡1 | 5 | .. | 35.67 | 30.00 | Duotrav [NV] |

## ▪ TRAVOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5555J OP | ‡1 | 5 | .. | 35.67 | 30.00 | Duotrav [NV] |

## MYDRIATICS AND CYCLOPLEGICS

*Anticholinergics*

### ▪ ATROPINE SULFATE

**atropine sulfate monohydrate 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1093M NP | ‡1 | 2 | .. | 23.84 | 25.24 | Atropt [AS] |

## OCULAR VASCULAR DISORDER AGENTS

*Antineovascularisation agents*

### ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10505X | 1 | 5 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

12153P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

12131L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

12141B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

2168D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

12152N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13392***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

13151E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

13139M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

13146X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

13167B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

13164W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

13150D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

11991D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

12132M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**aflibercept 4 mg/0.1 mL injection, 0.1 mL vial**

13138L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

**aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe**

13141P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 890.17 | 30.00 | [a] Eylea [BN] |

## ▪ BROLUCIZUMAB

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system

(see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**brolucizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe**

12667Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 994.91 | 30.00 | Beovu [NV] |

## ▪ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13195L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 933.61 | 30.00 | Vabysmo [RO] |

## ▪ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13198P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 933.61 | 30.00 | Vabysmo [RO] |

## ▪ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only per eye. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the Continuing treatment criteria.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13177M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 933.61 | 30.00 | Vabysmo [RO] |

## ▪ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only per eye. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the Continuing treatment criteria.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13183W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 933.61 | 30.00 | Vabysmo [RO] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

1382R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

10138N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

10374B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13165X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13134G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13137K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13157L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

11471R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

11480F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

11981N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

11975G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13392***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Authority required (STREAMLINED)**

***13340***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13156K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13143R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## ▪ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13149C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13166Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 785.89 | 30.00 | [a] Lucentis [NV] |

## OTHER OPHTHALMOLOGICALS

*Other ophthalmologicals*

### ▪ CARBOMER-974P

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses**

5502N (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *29.28 | 30.00 | Poly Gel [AQ] |

**carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses**

8514D (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *29.28 | 30.00 | Poly Gel [AQ] |

### ▪ CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carbomer-980 0.2% eye gel, 10 g**

5503P (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 16.52 | 17.92 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | [B]3.67 | 20.19 | 17.92 | [a] Viscotears [UO] | |

**carbomer-980 0.2% eye gel, 10 g**

8384G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | .. | 16.52 | 17.92 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | [B]3.67 | 20.19 | 17.92 | [a] Viscotears [UO] | |

### ▪ CARBOMER-980

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

5504Q (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *30.66 | 30.00 | Viscotears Gel PF [UO] |

**carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses**

8578L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *30.66 | 30.00 | Viscotears Gel PF [UO] |

### ▪ CARBOMER-980

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for repeats will be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carbomer-980 0.2% eye gel, 10 g**

9210R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 11 | .. | 16.52 | 17.92 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | [B]3.67 | 20.19 | 17.92 | [a] Viscotears [UO] | |

### ▪ CARMELLOSE SODIUM

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5508X OP | ‡1 | 5 | .. | 16.14 | 17.54 | Refresh Liquigel [VE] |

**carmellose sodium 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5507W OP | ‡1 | 5 | .. | 16.14 | 17.54 | Refresh Tears Plus [VE] |

## ▪ CARMELLOSE SODIUM

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8593G NP | ‡1 | 5 | .. | 16.14 | 17.54 | Refresh Liquigel [VE] |

**carmellose sodium 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8548X NP | ‡1 | 5 | .. | 16.14 | 17.54 | Refresh Tears Plus [VE] |

## ▪ CARMELLOSE SODIUM

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2324H NP | 3 | 5 | .. | *26.67 | 28.07 | [a] Optifresh Plus [PP] |
| | | | [B]4.83 | *31.50 | 28.07 | [a] Celluvisc [VE] |

**carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5505R OP | 3 | 5 | .. | *26.67 | 28.07 | [a] Optifresh Plus [PP] |
| | | | [B]4.83 | *31.50 | 28.07 | [a] Celluvisc [VE] |

**carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2338C NP | 3 | 5 | .. | *26.67 | 28.07 | [a] Optifresh Tears [PP] |
| | | | [B]4.83 | *31.50 | 28.07 | [a] Cellufresh [VE] |

**carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5506T OP | 3 | 5 | .. | *26.67 | 28.07 | [a] Optifresh Tears [PP] |
| | | | [B]4.83 | *31.50 | 28.07 | [a] Cellufresh [VE] |

## ▪ CARMELLOSE SODIUM

**Note** The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11852T NP | ‡1 | 5 | .. | 24.54 | 25.94 | Evolve Carmellose [CX] |

**carmellose sodium 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11853W OP | ‡1 | 5 | .. | 24.54 | 25.94 | Evolve Carmellose [CX] |

## ▪ CARMELLOSE SODIUM

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9212W | ‡1 | 11 | .. | 16.14 | 17.54 | Refresh Liquigel [VE] |

**carmellose sodium 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9211T | ‡1 | 11 | .. | 16.14 | 17.54 | Refresh Tears Plus [VE] |

## ▪ CARMELLOSE SODIUM + GLYCEROL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5556K OP | ‡1 | 3 | .. | 16.14 | 17.54 | Optive [VE] |

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9355J NP | ‡1 | 3 | .. | 16.14 | 17.54 | Optive [VE] |

## ▪ CARMELLOSE SODIUM + GLYCEROL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9356K | ‡1 | 7 | .. | 16.14 | 17.54 | Optive [VE] |

## ▪ CICLOSPORIN

**Caution** It is recommended that the potential for immunosuppression with long term use of this drug be clinically reviewed after at least 24 months of treatment, if not already reviewed.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Chronic severe dry eye disease with keratitis

Treatment Phase: Initial treatment for up to the first 180 days of treatment

**Clinical criteria:**

- Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber, **AND**
- Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation, **AND**
- The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute, **AND**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines, **AND**
- Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.

**Population criteria:**

- Patient must be at least 18 years of age.

Prescribing instruction:

State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).

**Note** The Oxford scale, modified Oxford scale and Ocular Surface Disease Index (OSDI) were relied upon in the submission supporting initial PBS listing.

The Oxford scale uses a chart system consisting of a series of panels, labelled A to E in order of increasing severity. In each chart, staining is represented by dots. To grade staining, comparisons are made between the panels and the appearance of staining on the exposed interpalpebral conjunctiva and cornea of the patient. The details of the chart are presented in Figure

1 and, in a simplified form in Figure 4 (where the criteria, dot count and log columns are not displayed), in the following literature article: Bron A, Evans V, Smith, J. Grading of corneal and conjunctival staining in the context of other dry eye tests. Cornea. 2003;22(7):640-650.
The modified Oxford scale is as above, but with the first grade depiction (Grade 0), termed 'Grade 0.5'.
A list of equivalent scales to the Oxford scale is not provided. Prescribers should be satisfied that a scale other than the Oxford scale, if used, is equivalent to the Oxford scale.
The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function.
The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.
The OSDI questionnaire asks the following:
Presence of ocular symptoms - Have you experienced any of the following during the last week?
1. Eyes that are sensitive to light
2. Eyes that feel gritty
3. Painful or sore eyes
4. Blurred vision
5. Poor vision

Impact on daily activities - Have you had problems with your eyes limited you in performing any of the following during the last week?
1. Reading
2. Driving at night
3. Working with a computer or bank machine (ATM)
4. Watching TV

Environmental factors - Have your eyes felt uncomfortable in any of the following situations during the last week?
1. Windy conditions
2. Places or areas with low humidity (very dry)
3. Areas that are airconditioned

Rate responses on a scale of 0 to 4; 0 = none of the time, 1 = some of the time, 2 = half of the time, 3 = most of the time, and 4 = all of the time.
Further information on this index is in the following literature article: Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. Drug Information Journal. 1997;31:1436
The 'Dry Eye OSDI 'Questionnaire' app developed by Allergan Inc is available to download for iPhone.

**Note** If the maximum number of repeats stated in this listing is not requested in this application, further supplies can be obtained through this treatment phase listing to continue treatment for up to the first 180 days of treatment, but the OSDI score and CFS grade need not be re-stated. Alternatively, treatment may be continued under the 'Continuing treatment' phase listing, provided the patient meets all eligibility criteria specified in that treatment phase listing.

**Authority required**

Chronic severe dry eye disease with keratitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application, **AND**
- The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.

Prescribing instructions:

State in the first continuing treatment authority application for this drug:

(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application).

State in all continuing treatment authority applications:

(ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).

**ciclosporin 0.09% eye drops, 60 x 0.25 mL unit doses**

13284E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 82.88 | 30.00 | Cequa [RA] |

OP

**ciclosporin 0.1% eye drops, 30 x 0.3 mL unit doses**

12663L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 82.88 | 30.00 | Ikervis [CS] |

OP

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

1509K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 16.90 | 18.30 | [a] Poly-Tears [IQ] |
| | | [B]3.85 | 20.75 | 18.30 | [a] Tears Naturale [AQ] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

5520M (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 16.90 | 18.30 | [a] Poly-Tears [IQ] |
| | | [B]3.85 | 20.75 | 18.30 | [a] Tears Naturale [AQ] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

5521N (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *30.06 | 30.00 | Bion Tears [AQ] |

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

8299T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *30.06 | 30.00 | Bion Tears [AQ] |

## ▪ DEXTRAN-70 + HYPROMELLOSE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

9216C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 11 | .. | 16.90 | 18.30 | [a] Poly-Tears [IQ] |
| | | [B]3.85 | 20.75 | 18.30 | [a] Tears Naturale [AQ] |

## ▪ HYALURONATE SODIUM

**Note** The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

**Authority required (STREAMLINED)**

***4105***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hyaluronate sodium 0.1% eye drops, 10 mL**

2181T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.34 | 30.00 | Hylo-Fresh [AE] |

**hyaluronate sodium 0.1% eye drops, 10 mL**

2184Y (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.34 | 30.00 | Hylo-Fresh [AE] |

**hyaluronate sodium 0.2% eye drops, 10 mL**

2171G (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | .. | 34.34 | 30.00 | Hylo-Forte [AE] |

**hyaluronate sodium 0.2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2253N NP | ‡1 | 5 | .. | 34.34 | 30.00 | Hylo-Forte [AE] |

## ▪ HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% w/w eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11625W NP | ‡1 | 5 | .. | 15.90 | 17.30 | [a] In a Wink Moisturising [IQ] | [a] Revive Tears [PP] |
| | | | [B]3.41 | 19.31 | 17.30 | [a] Genteal [AQ] | |

**hypromellose 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2956N NP | ‡1 | 5 | .. | 16.90 | 18.30 | Methopt [AF] |

## ▪ HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% w/w eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11634H OP | ‡1 | 5 | .. | 15.90 | 17.30 | [a] In a Wink Moisturising [IQ] | [a] Revive Tears [PP] |
| | | | [B]3.41 | 19.31 | 17.30 | [a] Genteal [AQ] | |

**hypromellose 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5517J OP | ‡1 | 5 | .. | 16.90 | 18.30 | Methopt [AF] |

## ▪ HYPROMELLOSE

**Note** The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hypromellose 0.3% w/v eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11842G NP | ‡1 | 5 | .. | 24.54 | 25.94 | Evolve Hypromellose [CX] |

**hypromellose 0.3% w/v eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11849P OP | ‡1 | 5 | .. | 24.54 | 25.94 | Evolve Hypromellose [CX] |

## ▪ HYPROMELLOSE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**hypromellose 0.3% w/w eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11643T | ‡1 | 11 | .. | 15.90 | 17.30 | [a] In a Wink Moisturising [IQ] | [a] Revive Tears [PP] |
| | | | [B]3.41 | 19.31 | 17.30 | [a] Genteal [AQ] | |

**hypromellose 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9214Y | ‡1 | 11 | .. | 16.90 | 18.30 | Methopt [AF] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5519L (OP) | ‡1 | 5 | .. | 16.90 | 18.30 | [a] HPMC PAA [IQ] |
| | | | [B]4.65 | 21.55 | 18.30 | [a] Genteal gel [AQ] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8564R (NP) | ‡1 | 5 | .. | 16.90 | 18.30 | [a] HPMC PAA [IQ] |
| | | | [B]4.65 | 21.55 | 18.30 | [a] Genteal gel [AQ] |

## ▪ HYPROMELLOSE + CARBOMER-980

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9215B | ‡1 | 11 | .. | 16.90 | 18.30 | [a] HPMC PAA [IQ] |
| | | | [B]4.65 | 21.55 | 18.30 | [a] Genteal gel [AQ] |

## ▪ LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE

**Note** The in-use shelf life of Cationorm is 3 months from the date of opening.

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12612T (OP) (NP) | ‡1 | 5 | .. | 38.58 | 30.00 | Cationorm [CS] |

## ▪ OCRIPLASMIN

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested.

**Authority required**

Vitreomacular traction syndrome

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR
- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography, **AND**
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, **AND**
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, **AND**
- The condition must be previously untreated in the eye proposed for treatment, **AND**
- Patient must not have received prior vitrectomy in the eye proposed for treatment, **AND**
- Patient must be symptomatic.

The prescriber must state which eye(s) is being treated at the time of application.

**ocriplasmin 375 microgram/0.3 mL intraocular injection, 0.3 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11798Y | 1 | .. | .. | 3962.13 | 30.00 | Jetrea RTU [IJ] |

## ▪ PARAFFIN

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1750D NP | ‡1 | 5 | .. | 21.44 | 22.84 | Poly Visc [IQ] |
| | | | [B]1.26 | 22.70 | 22.84 | Refresh Night Time [VE] |

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5522P OP | ‡1 | 5 | .. | 21.44 | 22.84 | Poly Visc [IQ] |
| | | | [B]1.26 | 22.70 | 22.84 | Refresh Night Time [VE] |

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1754H NP | 2 | 5 | .. | *21.81 | 23.21 | Poly Visc [IQ] |

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5523Q OP | 2 | 5 | .. | *21.81 | 23.21 | Poly Visc [IQ] |

## ▪ PARAFFIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9218E | ‡1 | 11 | .. | 21.44 | 22.84 | Poly Visc [IQ] |
| | | | [B]1.26 | 22.70 | 22.84 | Refresh Night Time [VE] |

## ▪ PARAFFIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9217D | 2 | 11 | .. | *21.81 | 23.21 | Poly Visc [IQ] |

## ▪ PERFLUOROHEXYLOCTANE

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**perfluorohexyloctane 100% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11439C OP | 1 | 5 | .. | 34.49 | 30.00 | Novatears [AE] |

**perfluorohexyloctane 100% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11446K NP | 1 | 5 | .. | 34.49 | 30.00 | Novatears [AE] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5524R OP | ‡1 | 5 | .. | 15.71 | 17.11 | [a] Optix [PP] | [a] Systane [AQ] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8676P NP | ‡1 | 5 | .. | 15.71 | 17.11 | [a] Optix [PP] | [a] Systane [AQ] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13100L NP | 2 | 5 | .. | *33.93 | 30.00 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13113E OP | 2 | 5 | .. | *33.93 | 30.00 | Systane [AQ] |

## ▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9219F | ‡1 | 11 | .. | 15.71 | 17.11 | [a] Optix [PP] | [a] Systane [AQ] |

## ▪ RETINOL PALMITATE + PARAFFIN

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.

**retinol palmitate 0.0138% + paraffin eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2167C OP | 2 | 5 | .. | *25.87 | 27.27 | VitA-POS [AE] |

**retinol palmitate 0.0138% + paraffin eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2222Y NP | 2 | 5 | .. | *25.87 | 27.27 | VitA-POS [AE] |

## ▪ RETINOL PALMITATE + PARAFFIN

**Note** The in-use shelf life of VitA-POS is 6 months from the date of opening.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**retinol palmitate 0.0138% + paraffin eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2202X | 2 | 11 | .. | *25.87 | 27.27 | VitA-POS [AE] |

## ▪ SOY LECITHIN + TOCOPHEROL + VITAMIN A

**Authority required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations**

5545W OP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *35.03 | 30.00 | tearsagain [RB] |

**soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations**

9448G NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | .. | *35.03 | 30.00 | tearsagain [RB] |

# ▪ OTOLOGICALS

## ANTIINFECTIVES

*Antiinfectives*

### ▪ CIPROFLOXACIN

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have perforation of the tympanic membrane.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have a grommet in situ.

**ciprofloxacin 0.3% ear drops, 5 mL**

2480M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 38.15 | 30.00 | Ciloxan [NV] |

## CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

*Corticosteroids and antiinfectives in combination*

### ▪ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE

**framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

2781J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 16.75 | 18.15 | [a] Otodex [AV] |
| | | [B]2.25 | 19.00 | 18.15 | [a] Sofradex [SW] |

### ▪ TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN

**triamcinolone acetonide 0.09% + neomycin 0.225% + gramicidin 0.0225% + nystatin 90 000 units/mL ear drops, 7.5 mL**

2971J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 17.18 | 18.58 | [a] Otocomb Otic [LN] |
| | | [B]1.58 | 18.76 | 18.58 | [a] Kenacomb Otic [AS] |

**triamcinolone acetonide 0.1% + neomycin 0.25% + gramicidin 0.025% + nystatin 100 000 units/g ointment, 5 g**

2974M NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 15.90 | 17.30 | [a] Otocomb Otic [LN] |
| | | [B]2.66 | 18.56 | 17.30 | [a] Kenacomb Otic [AS] |

# ▪ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

## ANTIINFECTIVES

*Antiinfectives*

### ▪ FRAMYCETIN SULFATE

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

1440T (NP) (MW)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 16.25 | 17.65 | Soframycin [SW] |

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

5557L (OP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 16.25 | 17.65 | Soframycin [SW] |

# ▪ VARIOUS

## ▪ ALLERGENS

### ALLERGENS

*Allergen extracts*

### ▪ HONEY BEE VENOM

**honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10621B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 297.43 | 30.00 | Hymenoptera Honey Bee Venom [DE] |

**honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

2886X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 183.21 | 30.00 | Albey Bee Venom [DE] |

### ▪ PAPER WASP VENOM

**Note** Paper wasp venom is not European wasp venom

**paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10620Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 347.69 | 30.00 | Hymenoptera Paper Wasp Venom [DE] |

**paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

2918N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 183.21 | 30.00 | Albey Paper Wasp Venom [DE] |

### ▪ YELLOW JACKET VENOM

**yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10622C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 402.42 | 30.00 | Hymenoptera Yellow Jacket Venom [DE] |

**yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

2883R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 183.21 | 30.00 | Albey Yellow Jacket Venom [DE] |

## ▪ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Antidotes*

### ▪ NALOXONE

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

10783M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 35.10 | 30.00 | [a] Naloxone Hydrochloride (DBL) [PF]<br>[a] NALOXONE SXP [XN] | [a] Naloxone Juno [JU] |

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

10787R (DP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 35.10 | 30.00 | [a] Naloxone Hydrochloride (DBL) [PF] | [a] Naloxone Juno [JU] |

[a] NALOXONE SXP [XN]

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11077B DP | 1 | .. | .. | 36.96 | 30.00 | Prenoxad [FF] |

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11078C NP | 1 | .. | .. | 36.96 | 30.00 | Prenoxad [FF] |

## ▪ NALOXONE

**Note** Pharmaceutical Benefits that have the form naloxone 1.8 mg mg/actuation nasal spray, 2 x 1 actuation are equivalent for the purpose of substitution in case of a shortage.

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11816X DP | ‡1 | .. | .. | 49.93 | 30.00 | [a] Nyxoid [MF] |

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11817Y NP | ‡1 | .. | .. | 49.93 | 30.00 | [a] Nyxoid [MF] |

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13617Q DP | ‡1 | .. | .. | 109.76 | 30.00 | [a] Nyxoid (UK) [QY] |

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13621X NP | ‡1 | .. | .. | 109.76 | 30.00 | [a] Nyxoid (UK) [QY] |

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

## ▪ LANTHANUM

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9403X NP | 1 | 5 | .. | 260.66 | 30.00 | Fosrenol [TK] |

**lanthanum 750 mg chewable tablet, 6 x 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9404Y NP | 1 | 5 | .. | 389.55 | 30.00 | Fosrenol [TK] |

**lanthanum 1 g chewable tablet, 6 x 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9405B NP | 1 | 5 | .. | 437.53 | 30.00 | Fosrenol [TK] |

## ▪ PATIROMER

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

***14327***
Chronic hyperkalaemia
Treatment Phase: Continuing treatment
**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor.

**Treatment criteria:**
- Patient must not be undergoing dialysis.

**patiromer 8.4 g powder for oral liquid, 30 sachets**

13609G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 375.91 | 30.00 | Veltassa [CS] |

**patiromer 16.8 g powder for oral liquid, 30 sachets**

13613L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 375.91 | 30.00 | Veltassa [CS] |

## ▪ PATIROMER

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hyperkalaemia
Treatment Phase: Initial PBS-subsidised treatment (including grandfathered patients)
**Population criteria:**
- Patient must have stage 3 to stage 4 chronic kidney disease.

**Clinical criteria:**
- The condition must be inadequately controlled by a low potassium diet., **AND**
- Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; OR
- Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia.

**Treatment criteria:**
- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.

**patiromer 8.4 g powder for oral liquid, 30 sachets**

13610H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 375.91 | 30.00 | Veltassa [CS] |

**patiromer 16.8 g powder for oral liquid, 30 sachets**

13620W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 375.91 | 30.00 | Veltassa [CS] |

## ▪ SEVELAMER

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**
***5491***
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation
**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer carbonate 800 mg tablet, 180**

11856B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 187.28 | 30.00 | [a] Sevelamer Apotex [TX] | [a] Sevelamer Lupin [GQ] |

NP

**sevelamer hydrochloride 800 mg tablet, 180**

2142R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 187.28 | 30.00 | [a] Renagel [GZ] |

NP

## ▪ SUCROFERRIC OXYHYDROXIDE

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

10250L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 412.03 | 30.00 | Velphoro [VL] |

NP

*Detoxifying agents for antineoplastic treatment*

## ▪ FOLINIC ACID

**folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules**

1704Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 60.08 | 30.00 | Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

**folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules**

1610R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 54.82 | 30.00 | Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

## ▪ FOLINIC ACID

**Restricted benefit**

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

**folinic acid 15 mg tablet, 10**

2308L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 94.71 | 30.00 | Leucovorin Calcium (Hospira Pty Limited) [PF] |

## ▪ MESNA

**Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

**mesna 1 g/10 mL injection, 15 x 10 mL ampoules**

8079F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 140.26 | 30.00 | Uromitexan [BX] |

**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

8078E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 68.62 | 30.00 | Uromitexan [BX] |

*Drugs for treatment of hypercalcemia*

## ▪ PHOSPHORUS

**Authority required (STREAMLINED)**
***5089***
Hypophosphataemic rickets
**Authority required (STREAMLINED)**
***5114***
Vitamin D-resistant rickets
**Authority required (STREAMLINED)**
***5095***
Familial hypophosphataemia
**Authority required (STREAMLINED)**
***5123***
Hypercalcaemia

**phosphorus 500 mg effervescent tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2946C NP | 1 | 5 | .. | 81.36 | 30.00 | PHOSPHATE PHEBRA [FG] |

*Other therapeutic products*

## ▪ POLYLACTIC ACID

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe facial lipoatrophy
Treatment Phase: Initial PBS-subsidised treatment
**Clinical criteria:**
- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9475Q | 2 | 4 | .. | *386.89 | 30.00 | Sculptra [GA] |

## ▪ POLYLACTIC ACID

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.
**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe facial lipoatrophy
Treatment Phase: Maintenance PBS-subsidised treatment
**Clinical criteria:**
- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9476R | 2 | .. | .. | *386.89 | 30.00 | Sculptra [GA] |

# ▪ DIAGNOSTIC AGENTS

## URINE TESTS

## ▪ GLUCOSE AND KETONE INDICATOR URINE

**Restricted benefit**
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose and ketone indicator urine diagnostic strip, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3107M NP | 2 | 2 | .. | *20.77 | 22.17 | Keto-Diastix [DX] |

## ▪ GLUCOSE INDICATOR URINE

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose indicator urine diagnostic strip, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3104J NP | 2 | 2 | .. | *20.35 | 21.75 | Diastix [DX] |

# ▪ GENERAL NUTRIENTS

## OTHER NUTRIENTS

## ▪ MEDIUM CHAIN TRIGLYCERIDES

**Note** From 1 September 2022, the brand K.Quik has replaced the brand Betaquik.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6147***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Authority required (STREAMLINED)**

***6191***

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**medium chain triglycerides oral liquid, 15 x 225 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13108X NP | 2 | 5 | .. | *243.59 | 30.00 | K.Quik [VF] |

## ▪ MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6181***

Chylous ascites

**Authority required (STREAMLINED)**

***6134***

Chylothorax

**Authority required (STREAMLINED)**

***6164***

Fat malabsorption

**Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)**

***6203***

Hyperlipoproteinaemia type 1

**Authority required (STREAMLINED)**

***6155***

Intractable childhood epilepsy

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)**

***6135***

Cerebrospinal fluid glucose transporter defect

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)**

***6146***

Long chain fatty acid oxidation disorders

**medium chain triglycerides oral liquid, 250 mL bottle**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9327X NP | 8 | 5 | .. | *170.13 | 30.00 | Liquigen [SB] |

**medium chain triglycerides oral oil, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3128P NP | 2 | 5 | .. | *46.67 | 30.00 | MCT Oil [SB] |

## ▪ PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Population criteria:**

- Patient must be aged from 1 to 10 years inclusive.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 12 x 500 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11939J NP | 7 | 5 | .. | *1583.23 | 30.00 | Nutrini Peptisorb Energy [NU] |

*Fat/carbohydrates/proteins/minerals/vitamins, combinations*

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1521C NP | 12 | 5 | .. | *438.81 | 30.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2250K NP | 12 | 5 | .. | *438.81 | 30.00 | EleCare [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1180D NP | 8 | 5 | .. | *295.17 | 30.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| 8574G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | .. | *295.17 | 30.00 | EleCare [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1192R NP | 8 | 5 | .. | *295.17 | 30.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8575H NP | 8 | 5 | .. | *295.17 | 30.00 | EleCare [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2246F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | Neocate LCP [SB] |

NP

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9339M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *235.89 | 30.00 | EleCare LCP [AB] |

NP

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2560R (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | Neocate LCP [SB] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9340N (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *235.89 | 30.00 | EleCare LCP [AB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

1545H (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 12 | 5 | .. | *470.49 | 30.00 | Neocate Gold [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5466Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | Neocate Gold [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5467R

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | Neocate Gold [SB] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal

antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2900P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | [a] Alfamino [NT] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g**

13615N

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | [a] Alfamino [NT] |

## ▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2928D NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | [a] Alfamino [NT] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g**

13627F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *316.37 | 30.00 | [a] Alfamino [NT] |

## ▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6174***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6193***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6204***

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6137***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6182***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6194***

Biliary atresia

**Authority required (STREAMLINED)**

***6157***

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

***6205***

Chylous ascites

**Authority required (STREAMLINED)**

***6195***

Cystic fibrosis

**Authority required (STREAMLINED)**

***6158***

Enterokinase deficiency

**Authority required (STREAMLINED)**

***6166***

Proven fat malabsorption

**Authority required (STREAMLINED)**

***6148***

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

***6138***

Severe intestinal malabsorption including short bowel syndrome

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

8259Q

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *89.33 | 30.00 | Aptamil Gold+ Pepti-Junior [NU] |

## ▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

***6174***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6193***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

***6204***

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6137***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6182***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***6194***

Biliary atresia

**Authority required (STREAMLINED)**

***6157***

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

***6205***

Chylous ascites

**Authority required (STREAMLINED)**

***6195***

Cystic fibrosis

**Authority required (STREAMLINED)**

***6158***

Enterokinase deficiency

**Authority required (STREAMLINED)**

***6166***

Proven fat malabsorption

**Authority required (STREAMLINED)**

***6148***

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

***6138***

Severe intestinal malabsorption including short bowel syndrome

**Authority required (STREAMLINED)**

***6206***

Chylothorax

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2676W NP | 8 | 5 | .. | *136.37 | 30.00 | Alfaré [NT] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10152H NP | 8 | 5 | .. | *403.89 | 30.00 | Monogen [SB] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10155L NP | 8 | 5 | .. | *364.85 | 30.00 | Lipistart [VF] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10154K NP | 8 | 5 | .. | *264.77 | 30.00 | Peptamen Junior [NT] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula oral liquid, 12 x 500 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12948L NP | 12 | 5 | .. | *1552.65 | 30.00 | Nutrini Peptisorb [SB] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Hyperlipoproteinaemia type 1

**Restricted benefit**

Long chain fatty acid oxidation disorders

**Restricted benefit**

Chylous ascites

**Restricted benefit**

Chylothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1938B NP | 8 | 5 | .. | *364.85 | 30.00 | Lipistart [VF] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8478F NP | 8 | 5 | .. | *403.89 | 30.00 | Monogen [SB] |

*Carbohydrates*

## ▪ MODIFIED LONG CHAIN AMYLOPECTIN

**Restricted benefit**

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9386B NP | 4 | 5 | .. | *651.85 | 30.00 | Glycosade [VF] |

*Amino acids/carbohydrates/minerals/vitamins, combinations*

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

10522T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *343.89 | 30.00 | Alfamino Junior [NT] |

NP

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

11161K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *343.89 | 30.00 | Neocate Junior [SB] |

NP

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10527C NP | 8 | 5 | .. | *343.89 | 30.00 | Alfamino Junior [NT] |

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11183N NP | 8 | 5 | .. | *343.89 | 30.00 | Neocate Junior [SB] |

*Milk substitutes*

## ▪ MILK POWDER SYNTHETIC LOW CALCIUM

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Hypercalcaemia

**Population criteria:**

- Patient must be under the age of 4 years.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3092R NP | 8 | 5 | .. | *364.13 | 30.00 | Locasol [SB] |

*Other combinations of nutrients*

## ▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

11343B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 12 | 5 | .. | *501.81 | 30.00 | Neocate Syneo [SB] |

NP

## ▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

11331J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *337.17 | 30.00 | Neocate Syneo [SB] |

NP

## ▪ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Note** A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11340W NP | 8 | 5 | .. | *337.17 | 30.00 | Neocate Syneo [SB] |

## ▪ AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate without phenylalanine modified release tablet, 6 x 77**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12072J NP | 4 | 5 | .. | *1322.65 | 30.00 | PKU Easy Tablet [OH] |

## ▪ AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine powder for oral liquid, 30 x 20 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10806R NP | 4 | 5 | .. | *957.33 | 30.00 | PKU Go [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate without methionine modified release tablet, 6 x 77**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12006X NP | 5 | 5 | .. | *2962.27 | 30.00 | HCU Easy Tablet [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10683G NP | 7 | 5 | .. | *1850.21 | 30.00 | PKU Easy Microtabs [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate without phenylalanine and tyrosine modified release tablet, 6 x 77**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12015J NP | 4 | 5 | .. | *2402.29 | 30.00 | TYR Easy Tablet [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with fat, carbohydrate without valine, leucine and isoleucine modified release tablet, 6 x 77**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12014H NP | 5 | 5 | .. | *2962.27 | 30.00 | MSUD Easy Tablet [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3417W NP | 4 | 5 | .. | *2181.33 | 30.00 | HCU Anamix junior LQ [SB] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10632N NP | 5 | 5 | .. | *1827.22 | 30.00 | PKU Easy Shake & Go [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9330C NP | 4 | 5 | .. | *2181.33 | 30.00 | TYR Anamix junior LQ [SB] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements, without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10934L NP | 4 | 5 | .. | *2826.37 | 30.00 | TYR Easy Shake & Go [OH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g**

12650T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *336.09 | 30.00 | Essential Care Jr [QH] |

## ▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g**

12643K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *336.09 | 30.00 | Essential Care Jr [QH] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10715Y NP | 8 | 5 | .. | *1831.65 | 30.00 | GA1 Anamix Junior [NU] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2650L NP | 8 | 5 | .. | *666.53 | 30.00 | GA1 Anamix infant [SB] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10466W NP | 9 | 5 | .. | *2669.76 | 30.00 | XLYS, LOW TRY Maxamum [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

Proven glutaric aciduria type 1

**Restricted benefit**

Pyridoxine dependent epilepsy

**Clinical criteria:**

- Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9438R NP | 4 | 5 | .. | *1370.53 | 30.00 | GA gel [VF] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5484P NP | 4 | 5 | .. | *2060.49 | 30.00 | GA express 15 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2639X NP | 4 | 5 | .. | *1370.33 | 30.00 | HCU cooler 10 [VF] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2640Y NP | 4 | 5 | .. | *3359.17 | 30.00 | HCU cooler 20 [VF] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 125 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1548L NP | 3 | 5 | .. | *2559.90 | 30.00 | HCU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9133Q NP | 4 | 5 | .. | *2023.05 | 30.00 | HCU cooler 15 [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8677Q NP | 4 | 5 | .. | *1370.33 | 30.00 | HCU gel [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8744F NP | 4 | 5 | .. | *2559.93 | 30.00 | HCU express 15 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 29 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12273Y NP | 4 | 5 | .. | *3359.17 | 30.00 | HCU Lophlex [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10693T NP | 4 | 5 | .. | *1743.29 | 30.00 | HCU Anamix Junior [NU] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**Population criteria:**

- Patient must be an infant or a very young child.

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8417B NP | 8 | 5 | .. | *633.65 | 30.00 | HCU Anamix infant [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

**Restricted benefit**

Methylmalonic acidaemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8058D NP | 8 | 5 | .. | *633.65 | 30.00 | MMA/PA Anamix infant [SB] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3444G NP | 4 | 5 | .. | *1370.33 | 30.00 | MMA/PA gel [VF] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3443F NP | 4 | 5 | .. | *2559.93 | 30.00 | MMA/PA express 15 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

**Restricted benefit**

Methylmalonic acidaemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 18 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10730R NP | 8 | 5 | .. | *1743.25 | 30.00 | MMA/PA Anamix Junior [NU] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g tubs**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2806Q NP | 3 | 5 | .. | *1520.19 | 30.00 | PKU Lophlex Sensation 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 28 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12136R NP | 4 | 5 | .. | *1672.49 | 30.00 | PKU Lophlex [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5483N NP | 4 | 5 | .. | *868.05 | 30.00 | PKU squeezie [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9021T NP | 4 | 5 | .. | *1672.49 | 30.00 | PKU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9396M NP | 4 | 5 | .. | *1041.29 | 30.00 | PKU Anamix Junior LQ [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8846N NP | 4 | 5 | .. | *1269.61 | 30.00 | PKU Cooler 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10411Y NP | 4 | 5 | .. | *1691.81 | 30.00 | PKU Air 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2474F NP | 4 | 5 | .. | *1691.81 | 30.00 | PKU Cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8746H NP | 5 | 5 | .. | *852.02 | 30.00 | Easiphen [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9397N NP | 2 | 5 | .. | *680.23 | 30.00 | PKU Lophlex LQ 10 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2382J NP | 4 | 5 | .. | *849.17 | 30.00 | PKU Cooler 10 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2739E NP | 8 | 5 | .. | *1109.09 | 30.00 | XP Maxamum [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8591E NP | 4 | 5 | .. | *1270.29 | 30.00 | PKU express 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 34 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1909L NP | 4 | 5 | .. | *1691.81 | 30.00 | PKU express 20 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**
Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10258X NP | 4 | 5 | .. | *869.05 | 30.00 | PKU Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 28 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12274B NP | 4 | 5 | .. | *3359.17 | 30.00 | TYR Lophlex [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2674R NP | 4 | 5 | .. | *1370.33 | 30.00 | TYR cooler 10 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2701E NP | 4 | 5 | .. | *3359.17 | 30.00 | TYR cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8445L NP | 8 | 5 | .. | *633.65 | 30.00 | TYR Anamix infant [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 125 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1547K NP | 3 | 5 | .. | *2023.08 | 30.00 | TYR Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9132P NP | 4 | 5 | .. | *2023.05 | 30.00 | TYR cooler 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8631G NP | 4 | 5 | .. | *1370.33 | 30.00 | TYR gel [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8667E NP | 4 | 5 | .. | *2023.05 | 30.00 | TYR express 15 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10260B NP | 4 | 5 | .. | *1743.29 | 30.00 | TYR Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 28 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12285N NP | 4 | 5 | .. | *3359.17 | 30.00 | MSUD Lophlex [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2651M NP | 4 | 5 | .. | *1370.33 | 30.00 | MSUD cooler 10 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2654Q NP | 4 | 5 | .. | *3359.17 | 30.00 | MSUD cooler 20 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2380G NP | 8 | 5 | .. | *633.65 | 30.00 | MSUD Anamix infant [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 125 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1546J NP | 3 | 5 | .. | *2559.90 | 30.00 | MSUD Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL pouches**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2375B NP | 4 | 5 | .. | *2559.93 | 30.00 | MSUD cooler 15 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8057C NP | 8 | 5 | .. | *2240.21 | 30.00 | MSUD Maxamum [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 24 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8592F NP | 4 | 5 | .. | *1370.33 | 30.00 | MSUD gel [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8632H NP | 4 | 5 | .. | *2559.93 | 30.00 | MSUD express 15 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10259Y NP | 4 | 5 | .. | *1743.29 | 30.00 | MSUD Anamix Junior [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9499Y NP | 4 | 5 | .. | *2181.33 | 30.00 | MSUD Anamix Junior LQ [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 25 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11836Y NP | 4 | 5 | .. | *957.29 | 30.00 | PKU Explore 10 [VF] |

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11185Q NP | 8 | 5 | .. | *957.25 | 30.00 | PKU Anamix First Spoon [SB] |

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11859E NP | 8 | 5 | .. | *957.25 | 30.00 | PKU Explore 5 [VF] |

## ▪ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8479G NP | 8 | 5 | .. | *579.73 | 30.00 | PKU Anamix infant [SB] |

## ▪ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Note** The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11653H NP | 8 | 5 | .. | *616.13 | 30.00 | PKU Start [VF] |

## ▪ AMINO ACID FORMULA WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

**amino acid formula without phenylalanine 1 g tablet, 75**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8678R NP | 24 | 5 | .. | *1170.21 | 30.00 | Phlexy-10 [SB] |

## ▪ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

Maple syrup urine disease

**amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10161T NP | 12 | 5 | .. | *2966.49 | 30.00 | MSUD amino5 [VF] |

## ▪ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Restricted benefit**

Peroxisomal biogenesis disorders

**arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10036F NP | 4 | 5 | .. | *353.49 | 30.00 | keyomega [VF] |

## ▪ ARGININE WITH CARBOHYDRATE

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted benefit**

Urea cycle disorders

**arginine with carbohydrate containing 2 g arginine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5482M NP | 4 | 5 | .. | *667.85 | 30.00 | Arginine 2000 [VF] |

**arginine with carbohydrate containing 500 mg arginine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9437Q NP | 4 | 5 | .. | *447.89 | 30.00 | Arginine 500 [VF] |

**arginine with carbohydrate containing 5 g arginine powder for oral liquid, 30 x 7.6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10093F NP | 4 | 5 | .. | *881.13 | 30.00 | Arginine 5000 [VF] |

## ▪ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8369L NP | 8 | 5 | .. | *258.53 | 30.00 | Energivit [SB] |

## ▪ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10039J NP | 4 | 5 | .. | *454.61 | 30.00 | basecal 200 [VF] |

## ▪ CITRULLINE

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

**Restricted benefit**

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline 1 g tablet, 300**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10736C NP | ‡1 | 5 | .. | 1144.47 | 30.00 | Citrulline Easy [OH] |

## ▪ CITRULLINE WITH CARBOHYDRATE

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted benefit**

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5481L NP | 4 | 5 | .. | *447.89 | 30.00 | Citrulline 1000 [VF] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula powder for oral liquid, 2 x 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9329B NP | 6 | 5 | .. | *1032.81 | 30.00 | Essential Amino Acid Mix [SB] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2027Q NP | 5 | 5 | .. | *522.82 | 30.00 | Dialamine [SB] |

## ▪ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

**Restricted benefit**

Gyrate atrophy of the choroid and retina

**Restricted benefit**

Urea cycle disorders

**essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9385Y NP | 4 | 5 | .. | *1305.57 | 30.00 | EAA Supplement [VF] |

## ▪ GLYCINE WITH CARBOHYDRATE

**Restricted benefit**

Isovaleric acidaemia

**glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10195N NP | 4 | 5 | .. | *496.73 | 30.00 | Glycine500 [VF] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE

**Restricted benefit**

Tyrosinaemia

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 35 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11832R NP | 4 | 5 | .. | *4098.17 | 30.00 | TYR Sphere20 [VF] |

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 31 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12175T NP | 4 | 5 | .. | *3359.17 | 30.00 | Tylactin Build 20 [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

Tyrosinaemia

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10528D NP | 4 | 5 | .. | *3114.17 | 30.00 | Tylactin RTD [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11290F NP | 8 | 5 | .. | *2917.33 | 30.00 | Tylactin Complete [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11084J NP | 5 | 5 | .. | *1317.37 | 30.00 | PKU Restore [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2644E NP | 14 | 5 | .. | *1293.99 | 30.00 | Camino Pro Complete [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 49 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10652P NP | 4 | 5 | .. | *1579.93 | 30.00 | Camino Pro Bettermilk [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Restricted benefit**
Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10332T NP | 4 | 5 | .. | *1579.89 | 30.00 | PKU Glytactin RTD 15 [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11640P NP | 4 | 5 | .. | *1579.89 | 30.00 | PKU Glytactin RTD 15 Lite [QH] |

## ▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.

**Restricted benefit**
Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11287C NP | 2 | 5 | .. | *1074.87 | 30.00 | PKU Build 10 [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11279P NP | 4 | 5 | .. | *2084.93 | 30.00 | PKU Build 20 [QH] |

## ▪ GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

**Restricted benefit**
Phenylketonuria

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11071Q NP | 4 | 5 | .. | *1983.93 | 30.00 | PKU Sphere20 [VF] |

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 15 x 237 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13257R NP | 8 | 5 | .. | *1983.89 | 30.00 | PKU Sphere Liquid [VF] |

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11245W NP | 4 | 5 | .. | *1504.17 | 30.00 | PKU Sphere15 [VF] |

## ▪ GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Restricted benefit**
Phenylketonuria

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11844J NP | 10 | 5 | .. | *1504.17 | 30.00 | PKU GMPro LQ [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Requests seeking an increased maximum quantity (packs) up to 4 times that stated, may be authorised.

**Restricted benefit**

Ketogenic diet

**Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12635B NP | 4 | 5 | .. | *794.33 | 30.00 | K.Yo [VF] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10185C NP | 5 | 5 | .. | *939.57 | 30.00 | KetoCal 4:1 LQ [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12456N NP | 6 | 5 | .. | *1360.29 | 30.00 | KetoVie 4:1 [QH] |

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12464B NP | 6 | 5 | .. | *929.25 | 30.00 | KetoVie 3:1 [QH] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2652N NP | 24 | 5 | .. | *984.69 | 30.00 | KetoCal 3:1 [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9446E NP | 24 | 5 | .. | *984.69 | 30.00 | KetoCal 4:1 [SB] |

## ▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency, **AND**
- Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula, **AND**
- Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of: 'Ketogenic diet'.

This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12789D NP | 6 | 5 | .. | *1539.99 | 30.00 | KetoVie Peptide 4:1 [QH] |

## ▪ ISOLEUCINE WITH CARBOHYDRATE

**Restricted benefit**

Maple syrup urine disease

**isoleucine with carbohydrate containing 1 g isoleucine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9436P NP | 4 | 5 | .. | *365.53 | 30.00 | Isoleucine 1000 [VF] |

**isoleucine with carbohydrate containing 50 mg isoleucine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9134R NP | 4 | 5 | .. | *333.09 | 30.00 | Isoleucine 50 [VF] |

## ▪ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR

- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g**

8630F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 24 | 5 | .. | *417.57 | 30.00 | Carbohydrate Free Mixture [SB] |

## ▪ PHENYLALANINE WITH CARBOHYDRATE

**Restricted benefit**

Tyrosinaemia

**phenylalanine with carbohydrate containing 50 mg phenylalanine powder for oral liquid, 30 x 4 g sachets**

9384X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *447.89 | 30.00 | Phenylalanine 50 [VF] |

## ▪ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

Phenylketonuria

**protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches**

10658Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 5 | .. | *1826.22 | 30.00 | PKU Easy [OH] |

## ▪ PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A

**Authority required (STREAMLINED)**

***11070***

Chronic renal failure

**Population criteria:**

- Patient must be a child aged 3 years or older.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A oral liquid, 24 x 125 mL bottles**

12191P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | .. | *1329.09 | 30.00 | Renastep [VF] |

## ▪ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can**

8577K NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 120 | 5 | .. | *551.97 | 30.00 | RCF [AB] |

## ▪ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons**

9309Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | .. | *258.97 | 30.00 | ProZero [VF] |

**triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cartons**

9308X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | .. | *291.09 | 30.00 | ProZero [VF] |

**triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10189G NP | 2 | 5 | .. | *159.31 | 30.00 | Sno-Pro [SB] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3136C NP | 8 | 5 | .. | *239.25 | 30.00 | Duocal [SB] |

## ▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Authority required (STREAMLINED)**

***6165***

Chylous ascites

**Authority required (STREAMLINED)**

***6192***

Chylothorax

**Authority required (STREAMLINED)**

***6173***

Fat malabsorption

**Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)**

***6156***

Hyperlipoproteinaemia type 1

**Authority required (STREAMLINED)**

***6136***

Long chain fatty acid oxidation disorders

**triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9383W NP | 4 | 5 | .. | *160.05 | 30.00 | MCT Pro-Cal [VF] |

## ▪ TYROSINE WITH CARBOHYDRATE

**Note** This formulation is suitable for patients aged 3 and older.

**Restricted benefit**

Phenylketonuria

**tyrosine with carbohydrate containing 1 g tyrosine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9165J NP | 4 | 5 | .. | *447.89 | 30.00 | Tyrosine 1000 [VF] |

## ▪ VALINE WITH CARBOHYDRATE

**Restricted benefit**

Maple syrup urine disease

**valine with carbohydrate containing 1 g valine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9434M NP | 4 | 5 | .. | *365.53 | 30.00 | Valine 1000 [VF] |

**valine with carbohydrate containing 50 mg valine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9135T NP | 4 | 5 | .. | *333.09 | 30.00 | Valine 50 [VF] |

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS

**Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11200L NP | 1 | 5 | .. | 281.80 | 30.00 | Phlexy-Vits [SB] |

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10149E NP | 1 | 5 | .. | 254.41 | 30.00 | FruitiVits [VF] |

## ▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be an infant or a child.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9328Y NP | 6 | 5 | .. | *336.51 | 30.00 | Paediatric Seravit [SB] |

## ▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2870C NP | 4 | 5 | .. | *1364.09 | 30.00 | Renastart [VF] |

## ▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

8587Y

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 16 | 5 | .. | *873.97 | 30.00 | Kindergen [SB] |

# Palliative Care

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# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Other agents for local oral treatment*

#### BENZYDAMINE

**Authority required (STREAMLINED)**

***6197***

Painful mouth

**Clinical criteria:**

- Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5385K NP | ‡1 | 3 | .. | 21.70 | 23.10 | Difflam [IL] |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**Authority required (STREAMLINED)**

***6207***

For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5317W NP | 6 | 3 | .. | *55.35 | 30.00 | [a] Buscopan [VZ] | [a] HYOSCINE BUTYLBROMIDE-AFT [AE] |
| | | | | | | [a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ] | [a] HYOSCINE BUTYLBROMIDE SXP [XN] |

### PROPULSIVES

*Propulsives*

#### METOCLOPRAMIDE

**Authority required (STREAMLINED)**

***6084***

Nausea or gastric stasis

**Clinical criteria:**

- Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10762K NP | 4 | 2 | .. | *27.41 | 28.81 | Maxolon [IL] |

#### METOCLOPRAMIDE

**Restricted benefit**

For use in patients receiving palliative care

**metoclopramide hydrochloride 10 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12507G NP | 4 | 5 | .. | *23.77 | 25.17 | [a] APO-Metoclopramide [TX] | [a] EMEXLON [RW] |
| | | | | | | [a] Pramin [AF] | |
| | | | [B]14.20 | *37.97 | 25.17 | [a] Maxolon [IL] | |

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Bulk-forming laxatives*

#### RHAMNUS FRANGULA + STERCULIA

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5322D NP | ‡1 | 3 | .. | 23.96 | 25.36 | Normacol Plus [NE] |

*Osmotically acting laxatives*

## ▪ MACROGOL-3350

**Authority required (STREAMLINED)**

***6170***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5426N NP | 2 | 3 | .. | *28.13 | 29.53 | OsmoLax [KY] |

## ▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Authority required (STREAMLINED)**

***6171***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 13.125 g/25 mL + sodium chloride 350.7 mg/25 mL + sodium bicarbonate 178.5 mg/25 mL + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10127B NP | 2 | 3 | .. | *23.07 | 24.47 | Movicol Liquid [NE] |

**macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5389P NP | 2 | 3 | .. | *28.13 | 29.53 | [a] APOHEALTH Macrogol with Electrolytes [GX]<br>[a] Chemists' Own Macrogol with Electrolytes [RW]<br>[a] Molaxole [GO] | [a] APO-MACROGOL plus ELECTROLYTES [TX]<br>[a] Macrovic [RF] |
| | | | [B]4.24 | *32.37 | 29.53 | [a] Movicol [NE] | |

*Enemas*

## ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5331N NP | 2 | 3 | .. | *31.25 | 30.00 | Micolette [AE] |

*Peripheral opioid receptor antagonists*

## ▪ METHYLNALTREXONE

**Authority required (STREAMLINED)**

***6180***

Opioid-induced constipation

**Clinical criteria:**

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

**methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5423K NP | 7 | .. | .. | *244.48 | 30.00 | Relistor [LM] |

**methylnaltrexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5424L NP | 1 | .. | .. | 244.52 | 30.00 | Relistor [LM] |

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

*Acetic acid derivatives and related substances*



### INDOMETACIN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**indometacin 25 mg capsule, 50**

5377B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *19.65 | 21.05 | [a] Arthrexin [AF] |
| | | [B]4.04 | *23.69 | 21.05 | [a] Indocid [AS] |

*Propionic acid derivatives*

### IBUPROFEN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**ibuprofen 400 mg tablet, 30**

5368M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *21.06 | 22.46 | [a] APO-Ibuprofen 400 [TX] |
| | | [B]7.53 | *28.59 | 22.46 | [a] Brufen [GO] |

### NAPROXEN

**Restricted benefit**

Severe pain

**Treatment criteria:**

- Patient must be undergoing palliative care.

**Clinical criteria:**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

5397C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 123.68 | 30.00 | Phebra Naproxen Suspension [FF] |

### NAPROXEN

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**naproxen 1 g modified release tablet, 28**

5348L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 18.81 | 20.21 | [a] Proxen SR 1000 [IY] |
| | | [B]0.99 | 19.80 | 20.21 | [a] Naprosyn SR1000 [IX] |

**naproxen 250 mg tablet, 50**

5345H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *21.41 | 22.81 | Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

5347K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | .. | 17.46 | 18.86 | [a] Proxen SR 750 [IY] |
| | | [B]0.87 | 18.33 | 18.86 | [a] Naprosyn SR750 [IX] |

### NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**naproxen sodium 550 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5353R NP | 1 | 3 | .. | 17.95 | 19.35 | [a] Crysanal [IY] |
| | | | [B]1.61 | 19.56 | 19.35 | [a] Anaprox 550 [IX] |

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

### HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***11697***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12531M NP | 2 | 1 | .. | *39.71 | 30.00 | [a] Dilaudid-HP [MF] | [a] Hydromorphone-hameln-HP [HW] |
| | | | | | | [a] HYDROMORPHONE JUNO-HP [JU] | [a] MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ] |

**hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12493M NP | 2 | 1 | .. | *34.31 | 30.00 | [a] Dilaudid [MF] | [a] Hydromorphone-hameln [HW] |
| | | | | | | [a] HYDROMORPHONE JUNO [JU] | [a] MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ] |

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12565H NP | 1 | 1 | .. | 350.72 | 30.00 | [a] Hikma [LM] | [a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ] |

**hydromorphone hydrochloride 2 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12497R NP | 2 | 1 | .. | *31.35 | 30.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12484C NP | 2 | 1 | .. | *35.89 | 30.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12515Q NP | 2 | 1 | .. | *52.71 | 30.00 | Dilaudid [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate pentahydrate 10 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5393W NP | 1 | 2 | .. | 22.69 | 24.09 | Sevredol [MF] |

**morphine sulfate pentahydrate 20 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5394X NP | 1 | 2 | .. | 23.44 | 24.84 | Sevredol [MF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***11697***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12494N NP | 2 | 1 | .. | *32.73 | 30.00 | Morphine Juno [JU] |

**morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12470H NP | 2 | 1 | .. | *42.43 | 30.00 | Morphine Juno [JU] |

**morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12537W NP | 2 | 1 | .. | *58.59 | 30.00 | Morphine Juno [JU] |

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12472K NP | 2 | 1 | .. | *52.13 | 30.00 | Ordine 10 [MF] |

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12549L NP | 2 | 1 | .. | *47.03 | 30.00 | Ordine 5 [MF] |

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12548K NP | 2 | 1 | .. | *30.25 | 30.00 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12503C NP | 2 | 1 | .. | *33.55 | 30.00 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

***11697***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12502B NP | 2 | 1 | .. | *27.67 | 29.07 | [a] Morphine Juno [JU] |

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12499W NP | 2 | 1 | .. | *28.09 | 29.49 | [a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 10 mg modified release capsule, 28**

| 12501Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *37.13 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 100 mg modified release capsule, 28**

| 12529K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *102.01 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 120 mg modified release capsule, 14**

| 12512M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *79.57 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 20 mg modified release capsule, 28**

| 12539Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *38.93 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 30 mg modified release capsule, 14**

| 12490J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *37.89 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 50 mg modified release capsule, 28**

| 12489H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *62.85 | 30.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 60 mg modified release capsule, 14**

| 12487F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *53.11 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 90 mg modified release capsule, 14**

| 12514P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *60.41 | 30.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets**

| 12495P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *124.03 | 30.00 | MS Contin Suspension 100 mg [MF] |

**morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets**

| 12528J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *88.11 | 30.00 | MS Contin Suspension 20 mg [MF] |

**morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets**

| 12505E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *235.07 | 30.00 | MS Contin Suspension 200 mg [MF] |

**morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets**

| 12488G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *90.53 | 30.00 | MS Contin Suspension 30 mg [MF] |

**morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets**

| 12536T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *101.19 | 30.00 | MS Contin Suspension 60 mg [MF] |

**morphine sulfate pentahydrate 10 mg modified release tablet, 28**

| 12547J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *32.45 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 100 mg modified release tablet, 28**

| 12483B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *104.81 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 15 mg modified release tablet, 28**

| 12476P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | .. | .. | *44.43 | 30.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5391R NP | 2 | .. | .. | *228.37 | 30.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12500X NP | 2 | .. | .. | *53.15 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

**morphine sulfate pentahydrate 5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12492L NP | 2 | .. | .. | *31.71 | 30.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 60 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12544F NP | 2 | .. | .. | *79.59 | 30.00 | [a] MORPHINE MR APOTEX [TX]<br>[a] MS Contin [MF] | [a] Morphine MR Mylan [AF] |

## ▪ MORPHINE

**Caution** The risk of drug dependence is high.

Morphine sulfate pentahydrate 10 and 20 mg modified release capsules must not be co-prescribed with immediate release oral morphine, when it has been prescribed for the reduction of chronic breathlessness.

**Note** Treatment should be initiated by a specialist knowledgeable in the use of potent opioids for the management of chronic breathlessness.

**Note** Applications for an increased maximum quantity to provide for 1 month's supply of this drug will be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic Breathlessness

**Clinical criteria:**

- Patient must be receiving palliative care.

**morphine sulfate pentahydrate 10 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11760Y NP | 1 | .. | .. | 27.65 | 29.05 | Kapanol [YN] |

**morphine sulfate pentahydrate 20 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11761B NP | 1 | .. | .. | 28.55 | 29.95 | Kapanol [YN] |

## ▪ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12518W NP | 2 | .. | .. | *40.17 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12545G NP | 2 | .. | .. | *56.65 | 30.00 | OxyContin [MF] |

**oxycodone hydrochloride 20 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12510K NP | 2 | .. | .. | *57.13 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12538X NP | 2 | .. | .. | *83.81 | 30.00 | OxyContin [MF] |

**oxycodone hydrochloride 40 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12525F NP | 2 | .. | .. | *77.09 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 80 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12527H NP | 2 | .. | .. | *114.71 | 30.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

## ▪ OXYCODONE + NALOXONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12523D NP | 2 | .. | .. | *55.63 | 30.00 | Targin 10/5mg [MF] |

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12486E NP | 2 | .. | .. | *84.61 | 30.00 | Targin 20/10mg [MF] |

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12475N NP | 2 | .. | .. | *118.63 | 30.00 | Targin 40/20mg [MF] |

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12522C NP | 2 | .. | .. | *53.37 | 30.00 | Targin 5/2.5mg [MF] |

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12471J NP | 2 | .. | .. | *37.89 | 30.00 | Targin 2.5/1.25 mg [MF] |

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12540B NP | 2 | .. | .. | *64.33 | 30.00 | Targin 15/7.5mg [MF] |

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12532N NP | 2 | .. | .. | *96.91 | 30.00 | Targin 30/15 mg [MF] |

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12511L NP | 2 | .. | .. | *150.97 | 30.00 | Targin 60/30 [MF] |

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12498T NP | 2 | .. | .. | *158.31 | 30.00 | Targin 80/40 [MF] |

*Phenylpiperidine derivatives*

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 800 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10612M NP | 1 | .. | .. | 81.05 | 30.00 | Abstral [FK] |

**fentanyl 400 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10603C NP | 1 | .. | .. | 81.05 | 30.00 | Abstral [FK] |

**fentanyl 100 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10601Y NP | 2 | .. | .. | *145.21 | 30.00 | Abstral [FK] |

**fentanyl 200 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10600X NP | 2 | .. | .. | *145.21 | 30.00 | Abstral [FK] |

**fentanyl 300 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10606F NP | 1 | .. | .. | 81.05 | 30.00 | Abstral [FK] |

**fentanyl 600 microgram sublingual tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10604D NP | 1 | .. | .. | 81.05 | 30.00 | Abstral [FK] |

**fentanyl 400 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5402H NP | 1 | .. | .. | 89.74 | 30.00 | Actiq [TB] |

**fentanyl 600 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5403J NP | 1 | .. | .. | 70.13 | 30.00 | Actiq [TB] |

**fentanyl 800 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5404K NP | 1 | .. | .. | 70.13 | 30.00 | Actiq [TB] |

**fentanyl 200 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5401G NP | 1 | .. | .. | 89.74 | 30.00 | Actiq [TB] |

**fentanyl 1200 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5405L NP | 1 | .. | .. | 70.13 | 30.00 | Actiq [TB] |

**fentanyl 1600 microgram lozenge, 9**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5406M NP | 1 | .. | .. | 70.13 | 30.00 | Actiq [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 100 microgram orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10729Q NP | 2 | .. | .. | *76.67 | 30.00 | Fentora [TB] |

**fentanyl 200 microgram orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10697B NP | 2 | .. | .. | *76.67 | 30.00 | Fentora [TB] |

**fentanyl 400 microgram orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10739F NP | 2 | .. | .. | *55.11 | 30.00 | Fentora [TB] |

**fentanyl 600 microgram orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10722H NP | 2 | .. | .. | *55.11 | 30.00 | Fentora [TB] |

**fentanyl 800 microgram orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10723J NP | 2 | .. | .. | *55.11 | 30.00 | Fentora [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 600 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10613N NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 800 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10611L NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 100 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10602B NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 200 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10607G NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 400 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10608H NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 300 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10610K NP | 2 | .. | .. | *409.29 | 30.00 | Abstral [FK] |

**fentanyl 200 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5407N NP | 2 | .. | .. | *514.13 | 30.00 | Actiq [TB] |

**fentanyl 400 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5408P NP | 2 | .. | .. | *514.13 | 30.00 | Actiq [TB] |

**fentanyl 600 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5409Q NP | 2 | .. | .. | *376.91 | 30.00 | Actiq [TB] |

**fentanyl 800 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5410R NP | 2 | .. | .. | *376.91 | 30.00 | Actiq [TB] |

**fentanyl 1200 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5411T NP | 2 | .. | .. | *376.91 | 30.00 | Actiq [TB] |

**fentanyl 1600 microgram lozenge, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5412W NP | 2 | .. | .. | *376.91 | 30.00 | Actiq [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 800 microgram orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10738E NP | 2 | .. | .. | *284.71 | 30.00 | Fentora [TB] |

**fentanyl 100 microgram orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10684H NP | 2 | .. | .. | *443.09 | 30.00 | Fentora [TB] |

**fentanyl 200 microgram orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10698C NP | 2 | .. | .. | *443.09 | 30.00 | Fentora [TB] |

**fentanyl 400 microgram orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10737D NP | 2 | .. | .. | *284.71 | 30.00 | Fentora [TB] |

**fentanyl 600 microgram orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10713W NP | 2 | .. | .. | *284.71 | 30.00 | Fentora [TB] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**
Severe disabling pain
**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 75 microgram/hour patch, 5**

12474M (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *62.03 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 75 [JC] |

**fentanyl 75 microgram/hour patch, 5**

12517T (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *72.39 | 30.00 | [a] Fenpatch 75 [RW] |

**fentanyl 75 microgram/hour patch, 5**

12526G (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *62.03 | 30.00 | [a] Denpax [AF] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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[Your capital city]

**Authority required**
Severe disabling pain
**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 50 microgram/hour patch, 5**

12477Q NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *50.19 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 50 [JC] |

**fentanyl 50 microgram/hour patch, 5**

12513N NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *57.73 | 30.00 | [a] Fenpatch 50 [RW] |

**fentanyl 50 microgram/hour patch, 5**

12546H NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *50.19 | 30.00 | [a] Denpax [AF] |



## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 100 microgram/hour patch, 5**

12480W NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *85.43 | 30.00 | [a] Fenpatch 100 [RW] |

**fentanyl 100 microgram/hour patch, 5**

12509J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *72.59 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 100 [JC] |

**fentanyl 100 microgram/hour patch, 5**

12533P NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *72.59 | 30.00 | [a] Denpax [AF] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 12 microgram/hour patch, 5**

12491K (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *31.87 | 30.00 | [a] Denpax [AF] |

**fentanyl 12 microgram/hour patch, 5**

12530L (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *35.09 | 30.00 | [a] Fenpatch 12 [RW] |

**fentanyl 12 microgram/hour patch, 5**

12541C (NP)

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *31.87 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 12 [JC] |

## ▪ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 25 microgram/hour patch, 5**

12504D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *35.59 | 30.00 | [a] APO-Fentanyl [TX]<br>[a] Fentanyl Sandoz [SZ] | [a] Durogesic 25 [JC] |

**fentanyl 25 microgram/hour patch, 5**

12516R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *35.59 | 30.00 | [a] Denpax [AF] |

**fentanyl 25 microgram/hour patch, 5**

12521B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *39.69 | 30.00 | [a] Fenpatch 25 [RW] |

*Diphenylpropylamine derivatives*

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5399E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 26.67 | 28.07 | Aspen Methadone Syrup [AS] |

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5400F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 26.67 | 28.07 | Aspen Methadone Syrup [AS] |

## ▪ METHADONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
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Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

12481X NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 24 | .. | .. | *906.35 | 30.00 | Physeptone [AS] |

**methadone hydrochloride 10 mg tablet, 20**

12520Y NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | .. | .. | *49.97 | 30.00 | Physeptone [AS] |

*Oripavine derivatives*

## ▪ BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note Shared Care Model**:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**buprenorphine 10 microgram/hour patch, 2**

10948F NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *51.39 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 20 microgram/hour patch, 2**

10970J NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | .. | .. | *69.43 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 5 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10957Q NP | 2 | .. | .. | *36.63 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 15 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10953L NP | 2 | .. | .. | *60.41 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 25 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10964C NP | 2 | .. | .. | *77.97 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 30 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10949G NP | 2 | .. | .. | *86.51 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

**buprenorphine 40 microgram/hour patch, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10959T NP | 2 | .. | .. | *103.61 | 30.00 | [a] Bupredermal [TX]<br>[a] Norspan [MF] | [a] Buprenorphine Sandoz [SZ] |

## OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

### ▪ PARACETAMOL

**Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 500 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12210P NP | 10 | 3 | .. | *97.97 | 30.00 | Panadol [GJ] |

### ▪ PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 665 mg modified release tablet, 192**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10796F NP | 1 | 3 | .. | 20.52 | 21.92 | [a] Osteomol 665 Paracetamol [CR] |

**paracetamol 665 mg modified release tablet, 96**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5343F NP | 2 | 3 | .. | *20.51 | 21.91 | [a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX]<br>[a] Osteomol 665 Paracetamol [CR] | [a] CHEMISTS' OWN OSTEO RELIEF PARACETAMOL [RF]<br>[a] Parapane OSTEO [AF] |

# ▪ ANTIEPILEPTICS

## ANTIEPILEPTICS

*Benzodiazepine derivatives*

### ▪ CLONAZEPAM

**Restricted benefit**

For use in patients receiving palliative care

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12534Q NP | 1 | 1 | .. | 23.56 | 24.96 | Rivotril [PB] |

## ▪ CLONAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients receiving palliative care

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5339B NP | 2 | 3 | .. | *20.51 | 21.91 | Rivotril [PB] |

**clonazepam 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5338Y NP | 1 | 3 | .. | 22.48 | 23.88 | Paxam 2 [AF] |

## ▪ CLONAZEPAM

**Note** Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

For use in patients receiving palliative care

**clonazepam 500 microgram tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11520H NP | 2 | 3 | [B]1.84 | *21.61 | 21.17 | [a] Rivotril [PB] |

**clonazepam 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5337X NP | 1 | 3 | .. | 19.76 | 21.16 | [a] Paxam 0.5 [AF] |

# ▪ PSYCHOLEPTICS

## ANTIPSYCHOTICS

*Butyrophenone derivatives*

## ▪ HALOPERIDOL

**Note Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

For use in patients receiving palliative care

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12519X NP | 1 | 2 | .. | 24.19 | 25.59 | Serenace [AS] |

## ANXIOLYTICS

*Benzodiazepine derivatives*

## ▪ DIAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving palliative care.

**diazepam 2 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5355W NP | 1 | 3 | .. | 15.90 | 17.30 | [a] APO-Diazepam [TX]<br>[a] Valpam 2 [RW] | [a] APX-Diazepam [TY] |
| | | | [B]2.78 | 18.68 | 17.30 | [a] Antenex 2 [AF] | |

**diazepam 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5356X NP | 1 | 3 | .. | 15.90 | 17.30 | [a] Antenex 5 [AF] | [a] APO-Diazepam [TX] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | [a] APX-Diazepam [TY] | [a] NOUMED DIAZEPAM [VO] |
| | | | | | [a] Valpam 5 [RW] | |
| NP | | [B]3.08 | 18.98 | 17.30 | [a] Valium [IX] | |

## ▪ OXAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving palliative care.

**oxazepam 15 mg tablet, 25**

5371Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 3 | .. | *18.41 | 19.81 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

5372R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 3 | .. | *18.41 | 19.81 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | [B]1.68 | *20.09 | 19.81 | [a] Murelax [RW] | |
| | | [B]7.84 | *26.25 | 19.81 | [a] Serepax [AS] | |

## HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

## ▪ NITRAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

**nitrazepam 5 mg tablet, 25**

5359C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 3 | .. | *18.41 | 19.81 | [a] Alodorm [AF] | [a] Mogadon [IL] |

## ▪ TEMAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving palliative care.

**temazepam 10 mg tablet, 25**

5375X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 3 | .. | *18.41 | 19.81 | [a] APO-Temazepam [TX] | [a] Temaze [AF] |
| | | | | | [a] Temtabs [LN] | |
| | | [B]10.14 | *28.55 | 19.81 | [a] Normison [AS] | |

# Repatriation Pharmaceutical Benefits Scheme

## BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

**Gold card**
This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

**White card**
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

**Orange card**
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au

# RPBS Explanatory Notes
## Introduction

### *The Australian Repatriation System*

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

## RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

### *Prior Approval Arrangements*

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

### *Palliative Care Drugs*

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine

- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide

- For further information telephone VAPAC on 1800 552 580.

### *Dental Prescribing*

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

### *Prescribing by optometrists*

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

## Provisions governing pricing and payment for RPBS benefits

### *Introduction*

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

### *Pricing of Schedule Items*

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

### *Pricing of Non-Schedule Ready Prepared Items*

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

### *Pricing of Non-Schedule Extemporaneously Prepared Items*

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

### *Miscellaneous Pricing Rules*

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

## General

### *Packaging Material, Postage or Freight*

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

### *Payment for Items Supplied at Short Intervals*

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

### *Receipts for Patient Charges*

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

### *Special Patient Contributions*

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

### *Therapeutic Group Premiums — Authority Processing*

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

# Contact the Department of Veterans' Affairs

**Authority Prescription Applications**

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

**For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580**
**Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.**

# WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

**DRESSINGS**

**Pink Epithelialising Wound**

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

| | | |
|---|---|---|
| (A) Covering | • Film;<br>• Film Island | • Gauze—Paraffin;<br>• Non-adherent |
| (B) Absorbing | • Foam (Light Exudate);<br>• Hydroactive (Superficial Wound—Light Exudate) | • Hydrocolloid (Superficial Wound—Light Exudate) |

**Red Granulating Wound**

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

| LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | • Foam (Light Exudate);<br>• Hydroactive (Superficial Wound—Light Exudate);<br>• Hydrocolloid (Superficial Wound—Light Exudate) | • Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Alginate (Superficial Wound);<br>• Foam—Heavy Exudate;<br>• Hydroactive (Superficial Wound—Moderate Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate/High Exudate) | • Alginate (Cavity Wound);<br>• Foam—Moderate Exudate (see “cavity conforming” product);<br>• Hydroactive (Cavity Wound);<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

**Yellow Sloughy Wound**

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

| LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | • Cadexomer Iodine;<br>• Foam—Light Exudate;<br>• Foam with Charcoal;<br>• Hydroactive (Superficial Wound—Moderate Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate Exudate) | • Cadexomer Iodine;<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture Donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Alginate (Superficial Wound);<br>• Cadexomer Iodine;<br>• Foam—Heavy Exudate;<br>• Hydroactive (Superficial Wound—Moderate/High Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate/High Exudate) | • Alginate (Cavity Wound);<br>• Cadexomer Iodine;<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

**Black Necrotic Wound**
Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

| DRY / LIGHT EXUDATE: | Superficial | Cavity |
|---|---|---|
| (A) Absorbing | • Hydroactive (Superficial Wound—Light Exudate);<br>• Hydrocolloid (Superficial Wound—Light/Moderate Exudate) | • Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet |

**Infected Wounds**
Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

**Malodorous Wounds**
Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.
Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

**Minor Skin Trauma**
Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

# Ordering Products

**Ordering Coloplast Products**
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Ordering Hartmann Products**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Ordering Molnlycke Healthcare Products**
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Ordering Smith & Nephew Products**
Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### CHLORHEXIDINE

**chlorhexidine gluconate 0.2% mouthwash, 250 mL**

4161B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 17.83 | 7.30 | Plaqacide [OB] |

**chlorhexidine gluconate 0.2% mouthwash, 300 mL**

4204G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.69 | 7.30 | Savacol Mouth and Throat Rinse [OM] |

#### NYSTATIN

**nystatin 100 000 units/mL oral liquid, 24 mL**

10854G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 1 | .. | 19.47 | 7.30 | [a] Pharmacy Action Nystatin Oral Drops [GQ] | [a] Trust Nystatin Oral Drops [CR] |
| | | .. | 20.71 | 7.30 | [a] Mycostatin Oral Drops [LN] | |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

*Synthetic anticholinergics, esters with tertiary amino group*

#### MEBEVERINE

**mebeverine hydrochloride 135 mg tablet, 90**

4328T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 30.81 | 7.30 | [a] APO-Mebeverine [TX] | [a] Colese [AF] |
| | | .. | 35.31 | 7.30 | [a] Colofac [GO] | |

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

4279F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 20.05 | 7.30 | [a] Buscopan [VZ] | [a] HYOSCINE BUTYLBROMIDE MEDSURGE [DZ] |
| | | | | | [a] HYOSCINE BUTYLBROMIDE SXP [XN] | |

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Softeners, emollients*

#### DOCUSATE

**docusate sodium 50 mg tablet, 100**

4200C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 19.85 | 7.30 | Coloxyl 50 [AS] |

*Contact laxatives*

#### BISACODYL

**bisacodyl 10 mg suppository, 10**

10578R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *25.62 | 7.30 | [a] Petrus Bisacodyl Suppositories [PP] |
| | | .. | *26.91 | 7.30 | [a] Dulcolax [VZ] |

RPBS

**bisacodyl 10 mg suppository, 12**

10580W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 4 | .. | *24.27 | 7.30 | Petrus Bisacodyl Suppositories [PP] |

## ▪ DOCUSATE + SENNOSIDE B

**docusate sodium 50 mg + sennoside B 8 mg tablet, 90**

10177P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | .. | 18.83 | 7.30 | [a] Pharmacy Action Colox-Senna [HQ] | [a] Pharmacy Action Laxative with Senna [GQ] |
| | | .. | 18.87 | 7.30 | [a] Chemists' Own Laxative with Senna [RW] | [a] Colaxsen [AS] |
| | | | | | [a] Coloxyl with Senna [LN] | [a] Co-Senna [PP] |
| | | | | | [a] Trust Coloxease [CR] | |

## ▪ SENNOSIDE B

**sennoside B 7.5 mg tablet, 100**

4455L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 18.39 | 7.30 | [a] Senna-Gen [PP] |
| | | .. | 19.46 | 7.30 | [a] Senokot [RC] |

*Bulk-forming laxatives*

## ▪ DRY PSYLLIUM HUSK

**dry psyllium husk 3.5 g powder for oral liquid, 30 sachets**

4285M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 22.75 | 7.30 | Fybogel [RC] |

## ▪ PSYLLIUM HUSK POWDER

**psyllium husk powder 3.4 g/7 g powder for oral liquid, 504 g**

12596Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 32.77 | 7.30 | Metamucil Natural Granular [PY] |

**psyllium husk powder 3.4 g/5.9 g powder for oral liquid, 283 g**

4419N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 26.25 | 7.30 | Metamucil Orange Smooth [PY] |

## ▪ RHAMNUS FRANGULA + STERCULIA

**rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

4558X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 23.96 | 7.30 | Normacol Plus [NE] |

*Enemas*

## ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL**

4462W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 17.99 | 7.30 | Micolette [AE] |

*Other drugs for constipation*

## ▪ GLYCEROL

**glycerol 1.4 g suppository, 12**

10596Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *25.23 | 7.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

**glycerol 2.8 g suppository, 12**

4246L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *25.71 | 7.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

**glycerol 700 mg suppository, 12**

10586E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 5 | .. | *24.87 | 7.30 | Petrus Pharmaceuticals Pty Ltd [PP] |

# ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

## ANTIPROPULSIVES

*Antipropulsives*

### LOPERAMIDE

**loperamide hydrochloride 2 mg capsule, 20**

11135C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 14.79 | 7.30 | [a] Gastrex [CR] | [a] Pharmacy Action Diarrhoea Relief [GQ] |

**loperamide hydrochloride 2 mg capsule, 12**

10592L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 14.48 | 7.30 | Gastrex [CR] |

# ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

## ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

*Peripherally acting antiobesity products*

### ORLISTAT

**Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

**Authority required**

Obesity

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

**Authority required**

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**Authority required**

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their inital body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**orlistat 120 mg capsule, 84**

4570M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 135.65 | 7.30 | Xenical [PB] |

# VITAMINS

## VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

*Vitamin B1, plain*

### ▪ THIAMINE

**thiamine hydrochloride 100 mg tablet, 100**

4043T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 16.88 | 7.30 | Betavit [PP] |

## VITAMIN B-COMPLEX, INCL. COMBINATIONS

*Vitamin B-complex, plain*

### ▪ LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE

**lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL oral liquid, 200 mL**

4493L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 19.01 | 7.30 | Accomin Adult Tonic [PF] |

# ▪ MINERAL SUPPLEMENTS

## CALCIUM

*Calcium*

### ▪ CALCIUM

**Restricted benefit**

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

11845K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *29.07 | 7.30 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 120**

4142B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *24.13 | 7.30 | [a] Cal-care 600 mg [CR] |
| | | .. | *26.77 | 7.30 | [a] CAL-600 [PP] |

### ▪ CALCIUM

**Restricted benefit**

Hypocalcaemia

**Restricted benefit**

Osteoporosis

**Restricted benefit**

Proven calcium malabsorption

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

11862H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 21.03 | 7.30 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 120**

4082W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 18.56 | 7.30 | [a] Cal-care 600 mg [CR] |
| | | .. | 19.88 | 7.30 | [a] CAL-600 [PP] |

## OTHER MINERAL SUPPLEMENTS

*Magnesium*

### ▪ MAGNESIUM

**Restricted benefit**

Hypomagnesaemia

The condition must be documented in the patient's medical records.

**magnesium 37.4 mg tablet, 50**

4321K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | .. | .. | 18.72 | 7.30 | Mag-Sup [PP] | |
| | | .. | 19.01 | 7.30 | Amcal Mag-A [IG] | Pharmacy Care Magnesium [SI] |
| | | .. | 19.58 | 7.30 | Magmin [BB] | |

# BLOOD AND BLOOD FORMING ORGANS

## ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

*Platelet aggregation inhibitors excl. heparin*

#### ASPIRIN

**aspirin 100 mg tablet, 112**

10590J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 15.11 | 7.30 | Spren 100 [OW] |

**aspirin 100 mg tablet, 90**

4076M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 21.03 | 7.30 | Cardiprin 100 [RC] |

#### ASPIRIN

**Note** The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

**aspirin 100 mg enteric capsule, 84**

4078P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 20.12 | 7.30 | Astrix [YN] |

**aspirin 100 mg enteric tablet, 84**

4077N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 19.33 | 7.30 | Cardasa [AF] | |
| | | | | | [a] Cartia [AS] | [a] Pharmacy Action Low Dose Aspirin [GQ] |
| | | | | | [a] Trust Aspirin EC 100 [CR] | |

#### CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Authority required**

For use in patients pre- and post-angioplasty

**clopidogrel 75 mg tablet, 28**

10169F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.08 | 7.30 | [a] BTC Clopidogrel [JB] | [a] Clopidogrel GH [GQ] |
| | | | | | [a] Plidogrel [RF] | |

**clopidogrel 75 mg tablet, 28**

4179Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | .. | 17.08 | 7.30 | [a] Clopidogrel Lupin [GQ] | [a] Clopidogrel Sandoz Pharma [HX] |
| | | | | | [a] Iscover [AV] | [a] Piax [AF] |
| | | | | | [a] Plavicor 75 [CR] | |

## ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

*Iron bivalent, oral preparations*

#### FERROUS FUMARATE

**ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60**

10594N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 19.32 | 7.30 | Ferro-tab [AE] |

*Iron in combination with folic acid*

#### FERROUS FUMARATE + FOLIC ACID

**ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60**

10579T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 20.29 | 7.30 | Ferro-f-tab [AE] |

### VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

## ▪ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin $B_{12}$ deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10577Q | 1 | .. | .. | 17.37 | 7.30 | [a] Vita-B12 [GH] |

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10587F | 1 | .. | .. | 17.37 | 7.30 | [a] Neo-B12 [PF] |

*Folic acid and derivatives*

## ▪ FOLIC ACID

**folic acid 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10584C | 2 | .. | .. | *17.19 | 7.30 | [a] Foltabs 500 [PP] | [a] Megafol 0.5 [AF] |

## ▪ FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**folic acid 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10573L | 2 | 1 | .. | *19.27 | 7.30 | Megafol 5 [AF] |

# ▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

## IRRIGATING SOLUTIONS

*Salt solutions*

## ▪ SODIUM CHLORIDE

**sodium chloride 0.9% (9 g/L) solution, 1 L bottle**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4461T | ‡1 | 2 | .. | 16.82 | 7.30 | Baxter Healthcare Pty Ltd [BX] |

**sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4460R | ‡1 | 2 | .. | 16.56 | 7.30 | Baxter Healthcare Pty Ltd [BX] |

RPBS

# ▪ CARDIOVASCULAR SYSTEM

# ▪ VASOPROTECTIVES

## AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

*Other agents for treatment of hemorrhoids and anal fissures for topical use*

## ▪ ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

**zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4039N | ‡1 | 1 | .. | 19.96 | 7.30 | Anusol [JT] |

**zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4040P | ‡1 | 1 | .. | 19.02 | 7.30 | Anusol [JT] |

# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

*Imidazole and triazole derivatives*

#### CLOTRIMAZOLE

**clotrimazole 1% cream, 20 g**

4004R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 15.04 | 7.30 | [a] Pharmacy Action Anti-Fungal Cream [GQ] |
| | | .. | 15.35 | 7.30 | [a] Clonea [AF] |

*Other antifungals for topical use*

#### AMOROLFINE

**Restricted benefit**

Onychomycosis

**amorolfine 5% solution, 5 mL**

4010C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 1 | .. | 49.55 | 7.30 | [a] Myconail [AE] | [a] Pharmacy Action Anti-Fungal Nail Treatment [GQ] |
| | | .. | 85.80 | 7.30 | [a] Aporyl [TX] | |
| | | .. | 94.55 | 7.30 | [a] Loceryl [GA] | |

#### TERBINAFINE

**Restricted benefit**

Tinea pedis

**terbinafine hydrochloride 1% cream, 15 g**

4473K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 1 | .. | 26.44 | 7.30 | [a] Lamisil [GJ] | [a] Pharmacy Action Pharmisil [GQ] |
| | | | | | [a] Trust Terbinafine Cream [CR] | |

**terbinafine 1% gel, 15 g**

4463X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 27.71 | 7.30 | Lamisil DermGel [GJ] |

#### TOLNAFTATE

**tolnaftate 0.07% spray, 100 g**

4481W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.53 | 7.30 | Tinaderm [BN] |

### ANTIFUNGALS FOR SYSTEMIC USE

*Antifungals for systemic use*

#### TERBINAFINE

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

**terbinafine 250 mg tablet, 42**

4011D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 28.35 | 7.30 | [a] APO-Terbinafine [TX] | [a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] |
| | | | | | [a] Tamsil [RW] | [a] Terbinafine Sandoz [SZ] |
| | | | | | [a] Tinasil [AF] | |

## EMOLLIENTS AND PROTECTIVES

### EMOLLIENTS AND PROTECTIVES

*Soft paraffin and fat products*

### ▪ WOOL ALCOHOLS

**wool alcohols 6% ointment, 100 g**

| 4041Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 19.74 | 7.30 | Eucerin [BE] |

*Carbamide products*

### ▪ UREA

**urea 10% cream, 100 g**

| 4042R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 18.07 | 7.30 | Aquacare H.P. [VE] |
| | | | .. | 18.27 | 7.30 | Urederm [KY] |

*Other emollients and protectives*

### ▪ GELATIN + PECTIN + CARMELLOSE SODIUM

**gelatin 16.7% + pectin 16.7% + carmellose sodium 16.7% paste, 5 g**

| 4518T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.79 | 7.30 | Orabase [AS] |

### ▪ GLYCEROL + WHITE SOFT PARAFFIN

**glycerol 5% + white soft paraffin 5% lotion, 1 L**

| 11712K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 32.19 | 7.30 | QV Skin Lotion [EO] |

### ▪ SKIN EMOLLIENT

**SKIN EMOLLIENT Bath oil 500 mL, 1**

| 4122Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 22.49 | 7.30 | Alpha Keri Bath Oil [MT] |
| | | | .. | 24.59 | 7.30 | QV Bath Oil [EO] |
| | | | .. | 24.67 | 7.30 | Hamilton Skin Therapy Oil [KY] |

**SKIN EMOLLIENT Lotion 500 mL, 1**

| 4107E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 22.49 | 7.30 | Alpha Keri Lotion [MT] |

## PROTECTIVES AGAINST UV-RADIATION

*Protectives against UV-radiation for topical use*

### ▪ BEMOTRIZINOL + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + HOMOSALATE + OCTOCRYLENE + TITANIUM DIOXIDE

**bemotrizinol 1.8% + diethylamino hydroxybenzoyl hexyl benzoate 4% + homosalate 8% + octocrylene 8% + titanium dioxide 2.5% lotion, 125 mL**

| 13188D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 23.10 | 7.30 | Sunsense Comfort SPF 50+ [EO] |

### ▪ SUNSCREENS

**SUNSCREENS Cream 75 g, 1**

| 4307Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 23.10 | 7.30 | Sunsense Sensitive SPF 50+ [EO] |

**SUNSCREENS Lotion (non-alcoholic) 125 mL, 1**

| 4546G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 21.30 | 7.30 | Aquasun Lotion SPF 18 [PF] |

# ▪ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

## ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

*Anesthetics for topical use*

### ▪ LIDOCAINE

**lidocaine hydrochloride 2% oral liquid, 200 mL**

| 4308R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 105.11 | 7.30 | Xylocaine Viscous [AS] |

*Other antipruritics*

### ▪ TAR + TROLAMINE LAURIL SULFATE

**Note** For patients who have failed to respond to simple moisturising agents.

**tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL**

4408B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 27.34 | 7.30 | Pinetarsol [EO] |

## ▪ ANTIPSORIATICS

### ANTIPSORIATICS FOR TOPICAL USE

*Tars*

### ▪ COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

**coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g**

4505D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 21.34 | 7.30 | Egopsoryl-TA [EO] |

## ▪ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

### ANTIBIOTICS FOR TOPICAL USE

*Other antibiotics for topical use*

### ▪ MUPIROCIN

**mupirocin 2% ointment, 15 g**

4350Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 21.61 | 7.30 | [a] Medicianz Mupirocin Ointment [DZ] |
| | | .. | 22.41 | 7.30 | [a] APO-Mupirocin [TX] |
| | | .. | 25.48 | 7.30 | [a] Bactroban [GK] |

### ▪ MUPIROCIN

**Restricted benefit**

Secondarily infected traumatic skin lesions

**mupirocin 2% cream, 15 g**

4348W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 25.48 | 7.30 | Bactroban [GK] |

## ▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

### ▪ HYDROCORTISONE ACETATE

**hydrocortisone acetate 1% cream, 30 g**

11710H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 1 | .. | 18.21 | 7.30 | [a] Pharmacy Action Hydrocortisone Cream 1% [GQ] | [a] Trust HydroCortic Cream [CR] |

### ▪ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% ointment, 30 g**

10831C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 18.21 | 7.30 | Cortic-DS 1% [AS] |

*Corticosteroids, potent (group III)*

### ▪ BETAMETHASONE VALERATE

**betamethasone (as valerate) 0.1% cream, 30 g**

4131K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 26.91 | 7.30 | Betnovate [AS] |

RPBS

**betamethasone (as valerate) 0.1% ointment, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4132L | ‡1 | 2 | .. | 26.91 | 7.30 | Betnovate [AS] |

## ▪ MOMETASONE

**Note** Application to large areas of skin for longer than four weeks is not recommended.

**mometasone furoate 0.1% cream, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4342M | ‡1 | .. | .. | 36.52 | 7.30 | Elocon Alcohol Free [AL] |

**mometasone furoate 0.1% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4343N | ‡1 | .. | .. | 36.52 | 7.30 | Elocon [AL] |

# ▪ ANTISEPTICS AND DISINFECTANTS

## ANTISEPTICS AND DISINFECTANTS

*Iodine products*

## ▪ POVIDONE-IODINE

**povidone-iodine 10% solution, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4411E | ‡1 | .. | .. | 26.63 | 7.30 | Betadine Antiseptic Liquid [SW] |

# ▪ OTHER DERMATOLOGICAL PREPARATIONS

## OTHER DERMATOLOGICAL PREPARATIONS

*Medicated shampoos*

## ▪ COAL TAR SOLUTION + SALICYLIC ACID

**coal tar solution 4.25% + salicylic acid 2% shampoo, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4560B | ‡1 | 2 | .. | 25.13 | 7.30 | Ionil-T [GA] |

## ▪ SELENIUM SULFIDE

**selenium sulfide 2.5% shampoo, 125 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4452H | ‡1 | .. | .. | 19.70 | 7.30 | Selsun [DQ] |

## ▪ TAR + COAL TAR SOLUTION + SALICYLIC ACID

**tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4447C | ‡1 | 2 | .. | 23.79 | 7.30 | Sebitar [EO] |

*Wart and anti-corn preparations*

## ▪ SALICYLIC ACID + LACTIC ACID

**salicylic acid 16.7% + lactic acid 15% solution, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11959K | ‡1 | .. | .. | 23.19 | 7.30 | Duofilm Solution [GK] |

*Other dermatologicals*

## ▪ DICLOFENAC

**Note** Maximum quantity of four tubes (original + 3 repeats) in 12 months.

**Authority required**

Solar (actinic) keratosis

Treatment Phase: Management

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**diclofenac sodium 3% gel, 25 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4046Y | ‡1 | 3 | .. | 60.05 | 7.30 | Solaraze 3% Gel [YN] |

## ▪ GLYCEROL

### glycerol 15% solution, 1 kg

11708F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 31.70 | 7.30 | QV Gentle Wash [EO] |

## ▪ ICHTHAMMOL

**Note** For patients who have failed to respond to simple moisturising agents.

### ichthammol 1% cream, 50 g

4281H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 23.15 | 7.30 | Egoderm Cream [EO] |

## ▪ ICHTHAMMOL + ZINC OXIDE

**Note** For patients who have failed to respond to simple moisturising agents.

### ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 23.15 | 7.30 | Egoderm Ointment [EO] |

## ▪ IMIQUIMOD

**Authority required**

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

### imiquimod 5% cream, 12 x 250 mg sachets

4559Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 88.52 | 7.30 | [a] Aldiq [AF] | [a] APO-Imiquimod [TX] |
| | | .. | 91.82 | 7.30 | [a] Aldara [IL] | |

## ▪ IMIQUIMOD

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**

Solar keratosis

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

### imiquimod 5% cream, 2 x 2 g

10106X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 96.87 | 7.30 | [a] Aldara Pump [IL] |

### imiquimod 5% cream, 12 x 250 mg sachets

4134N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 88.52 | 7.30 | [a] Aldiq [AF] | [a] APO-Imiquimod [TX] |
| | | .. | 91.82 | 7.30 | [a] Aldara [IL] | |

## ▪ LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

### light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

4549K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 25.44 | 7.30 | Hamilton Skin Therapy Wash [KY] |

## ▪ PANTHENOL

**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

### panthenol conditioner, 200 g

4510J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 19.80 | 7.30 | SebiRinse [EO] |

### ▪ ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN

**zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% powder, 100 g**

4497Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 18.12 | 7.30 | Z.S.C. [RW] |

# ▪ GENITO URINARY SYSTEM AND SEX HORMONES

## ▪ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

### ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

*Antibiotics*

### ▪ NYSTATIN

**nystatin 20 000 units/g vaginal cream, 75 g**

4013F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 19.40 | 7.30 | Nilstat [AS] |

*Imidazole derivatives*

### ▪ CLOTRIMAZOLE

**clotrimazole 2% vaginal cream, 20 g**

4017K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.52 | 7.30 | [a] APO-Clotrimazole 3 Day Cream [TX] | [a] Clonea 3 Day Cream [AF] |
| | | | | | [a] Pharmacy Action FemCream 3 Day Cream [GQ] | [a] Trust Fem V 3 Day Cream [CR] |

**clotrimazole 1% vaginal cream, 35 g**

4016J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | .. | .. | 19.31 | 7.30 | [a] Clonea 6 Day Cream [AF] | [a] Pharmacy Action FemCream [GQ] |
| | | | | | [a] Trust Fem V 6 Day Cream [CR] | |
| | | .. | 20.52 | 7.30 | [a] APO-Clotrimazole 6 Day Cream [TX] | |

## ▪ OTHER GYNECOLOGICALS

### OTHER GYNECOLOGICALS

### ▪ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

**acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g**

4434J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 36.02 | 7.30 | Aci-Jel [CU] |

## ▪ UROLOGICALS

### UROLOGICALS

*Drugs used in erectile dysfunction*

### ▪ ALPROSTADIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**alprostadil 10 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes**

4579B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *107.55 | 7.30 | Caverject Impulse [PF] |

RPBS

**alprostadil 20 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes**

4580C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *135.87 | 7.30 | Caverject Impulse [PF] |

## ▪ AVANAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**avanafil 100 mg tablet, 4**

11861G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 53.85 | 7.30 | Spedra [FK] |

**avanafil 200 mg tablet, 4**

11860F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 56.00 | 7.30 | Spedra [FK] |

**avanafil 50 mg tablet, 4**

11837B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 51.70 | 7.30 | Spedra [FK] |

## ▪ SILDENAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**sildenafil 100 mg tablet, 4**

4586J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 32.99 | 7.30 | [a] Sildenafil generichealth [GQ] | [a] Sildenafil Lupin [HQ] |
| | | | | | [a] Viagra [UJ] | |
| | | .. | 73.51 | 7.30 | [a] NOUMED Sildenafil [VO] | [a] Sildenafil APOTEX [GX] |
| | | | | | [a] Sildenafil Sandoz [SZ] | [a] Vasafil 100 [RW] |
| | | | | | [a] Vedafil [AF] | |

**sildenafil 25 mg tablet, 4**

4584G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 26.06 | 7.30 | [a] Viagra [UJ] | |
| | | .. | 56.94 | 7.30 | [a] Sildenafil APOTEX [GX] | [a] Sildenafil Sandoz [SZ] |
| | | | | | [a] Vasafil 25 [RW] | [a] Vedafil [AF] |

**sildenafil 50 mg tablet, 4**

4585H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 29.63 | 7.30 | [a] Sildenafil Lupin [HQ] | [a] Viagra [UJ] |
| | | .. | 68.94 | 7.30 | [a] NOUMED Sildenafil [VO] | [a] Sildenafil APOTEX [GX] |
| | | | | | [a] Sildenafil Sandoz [SZ] | [a] Vasafil 50 [RW] |
| | | | | | [a] Vedafil [AF] | |

## ▪ TADALAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**

- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**tadalafil 10 mg tablet, 4**

4596X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 105.75 | 7.30 | [a] Apo-Tadalafil [TX]<br>[a] Cidala [RW]<br>[a] Cipla Tadalafil [LR]<br>[a] Tadalafil Sandoz [SZ] | [a] Cialis [LY]<br>[a] Cilatil [AF]<br>[a] Tadalafil GH [GQ] |

**tadalafil 20 mg tablet, 4**

4597Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 105.75 | 7.30 | [a] Apo-Tadalafil [TX]<br>[a] Cidala [RW]<br>[a] Cipla Tadalafil [LR]<br>[a] Tadalafil GH [GQ] | [a] Cialis [LY]<br>[a] Cilatil [AF]<br>[a] Tadalaccord [CR]<br>[a] Tadalafil Sandoz [SZ] |

*Other urologicals*

## ▪ BICARBONATE + CITRIC ACID + TARTARIC ACID

**Note** Pharmaceutical benefits that have the forms sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid and sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules are equivalent for the purposes of substitution.

**Restricted benefit**

Urinary symptoms

**Clinical criteria:**

- The treatment must be for when antibiotic or other therapy alone is inappropriate.

**sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules, 28 x 4 g sachets**

12179B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 4 | .. | 19.19 | 7.30 | [a] Trust Cystitis Relief [CR] |

**sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets**

4049D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 4 | .. | 19.19 | 7.30 | [a] Pharmacy Action Cystitis Relief [GQ] | [a] Ural Sachets [AS] |

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

*Alpha-adrenoreceptor antagonists*

## ▪ ALFUZOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

4277D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 76.56 | 7.30 | Xatral SR [SW] |

## ▪ DUTASTERIDE + TAMSULOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

10102Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 34.39 | 7.30 | Duodart 500ug/400ug [GK] |

## ▪ SILODOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**silodosin 4 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12079R | 1 | 5 | .. | 39.78 | 7.30 | Urorec [YN] |

**silodosin 8 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12077P | 1 | 5 | .. | 44.53 | 7.30 | Urorec [YN] |

## ▪ TAMSULOSIN

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**tamsulosin hydrochloride 400 microgram modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4070F | 1 | 5 | .. | 64.75 | 7.30 | [a] Apo-Tamsulosin SR [TX] | [a] Blooms the Chemist Tamsulosin SR [IB] |
| | | | | | | [a] Flomaxtra [LS] | [a] Flosix [AF] |
| | | | | | | [a] Tamsulosin Sandoz SR [SZ] | |

*Testosterone-5-alpha reductase inhibitors*

## ▪ DUTASTERIDE

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**dutasteride 500 microgram capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10095H | 1 | 5 | .. | 29.35 | 7.30 | [a] APO-Dutasteride [TX] |
| | | | .. | 36.35 | 7.30 | [a] Avodart [GK] |

## ▪ FINASTERIDE

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**finasteride 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4303L | 1 | 5 | .. | 90.12 | 7.30 | Finpro [RZ] |

**finasteride 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4233T | 1 | 5 | .. | 77.78 | 7.30 | [a] Finasteride GH 5 [GQ] | [a] Finasteride Mylan 5 [AF] |
| | | | | | | [a] Finide [AL] | |
| | | | .. | 95.63 | 7.30 | [a] Finnacar [RW] | |
| | | | .. | 99.98 | 7.30 | [a] APO-Finasteride [TX] | [a] Finasta [SZ] |
| | | | | | | [a] Finasteride-GA 5 [GN] | [a] Pharmacor Finasteride 5 [CR] |
| | | | | | | [a] Proscar [OQ] | |

# ▪ ANTIINFECTIVES FOR SYSTEMIC USE

# ▪ ANTIBACTERIALS FOR SYSTEMIC USE

## MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

*Macrolides*

## ▪ AZITHROMYCIN

**Restricted benefit**

Upper and lower respiratory tract infections

**azithromycin 500 mg tablet, 3**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4115N | 1 | .. | .. | 34.81 | 7.30 | Zedd 500 [RW] | |
| | | | | | | [a] APO-Azithromycin [TX] | [a] Azithromycin Mylan [AF] |
| | | | | | | [a] Azithromycin Sandoz [SZ] | [a] ZITHRO [RF] |
| | | | | | | [a] Zithromax [PF] | |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

*Pyrimidine analogues*

#### FLUOROURACIL

**fluorouracil 5% cream, 20 g**

4222F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 67.18 | 7.30 | [a] APOC-5FU [TX] |
| | | .. | 76.21 | 7.30 | [a] Efudix [IL] |

## IMMUNOSUPPRESSANTS

### IMMUNOSUPPRESSANTS

*Tumor necrosis factor alpha (TNF-alpha) inhibitors*

#### INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab, or requests for forms, may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.
Written applications for authority to prescribe infliximab should be forwarded to:
Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

**Authority required**

Rheumatoid arthritis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

**Population criteria:**

- Patient must be an adult.

**Clinical criteria:**

- Patient must have active rheumatoid arthritis, **AND**
- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have a proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP) level, **AND**
- Patient must have proven erosive rheumatoid arthritis without end-stage disease, **AND**
- Patient must have failed an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or ciclosporin), unless these drugs were contraindicated or intolerance developed, **AND**
- Patient must have no history of active tuberculosis requiring treatment in the last 3 years, **AND**
- Patient must have no history of opportunistic infection in the last 2 months, **AND**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must be for the reduction of signs and symptoms and prevention of structural joint damage, **AND**
- Patient must not be pregnant or breastfeeding, **AND**
- Patient must be using an effective form of contraception if female and of child-bearing age.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

**Authority required**

Rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have previously been issued with an authority prescription for this drug for the treatment of this condition, **AND**
- Patient must have demonstrated an improvement in ESR and/or CRP level following the initial 3 dose course of therapy, **AND**
- Patient must have achieved an ACR20 (American College of Rheumatology) response by 14 weeks after the commencement of the initial course of therapy, **AND**

- The treatment must be in combination with methotrexate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

**infliximab 100 mg injection, 1 vial**

4284L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 285.56 | 7.30 | Remicade [JC] |

# MUSCULO-SKELETAL SYSTEM

## TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

*Preparations with salicylic acid derivatives*

**METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM EXTRACT**

**methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum extract 0.15% cream, 100 g**

11707E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 19.60 | 7.30 | Goanna Heat Cream [GQ] |

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

**RISEDRONATE**

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**risedronate sodium 35 mg enteric tablet, 4**

2191H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 7.30 | Actonel EC [TT] |

**risedronate sodium 5 mg tablet, 28**

4443W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 7.30 | Actonel [TT] |

**risedronate sodium 35 mg tablet, 4**

4444X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 37.00 | 7.30 | [a] APO-Risedronate [TX]<br>[a] Risedronate Sandoz [SZ] | [a] Risedronate-GA [GN] |

*Bisphosphonates, combinations*

**ALENDRONATE + COLECALCIFEROL**

**Authority required**

Preservation of bone mineral density

**Clinical criteria:**

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4**

2224C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.53 | 7.30 | [a] ALENDRONATE PLUS D3 70mg/140ug APOTEX [GX] | [a] Alendronate Plus D3 Sandoz [SZ] |
| | | .. | 21.73 | 7.30 | [a] Fosamax Plus 70 mg/140 mcg [MQ] | |

RPBS

**alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4**

2194L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | .. | 18.53 | 7.30 | [a] ALENDRONATE PLUS D3 70mg/70ug APOTEX [GX] | [a] Alendronate Plus D3 Sandoz [SZ] |
| | | .. | 21.73 | 7.30 | [a] Fosamax Plus [MQ] | |

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

4349X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 120.77 | 7.30 | MS Contin [MF] |

*Opioids in combination with non-opioid analgesics*

### ASPIRIN + CODEINE

**aspirin 300 mg + codeine phosphate hemihydrate 8 mg dispersible tablet, 40**

4286N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 19.74 | 7.30 | Aspalgin 40 [GO] |

### PARACETAMOL + CODEINE

**paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 40**

4275B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 18.51 | 7.30 | Panamax Co. 40 [SW] |

### OTHER ANALGESICS AND ANTIPYRETICS

*Anilides*

### PARACETAMOL

**paracetamol 48 mg/mL oral liquid, 200 mL**

10599W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 2 | .. | 16.84 | 7.30 | [a] Panamax 240 Elixir [SW] | [a] Trust for Kids Paracetamol 6 to 12 years [CR] |

**paracetamol 500 mg tablet, 100**

10582Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | .. | 14.66 | 7.30 | [a] APO-Paracetamol [TX] | [a] Febridol [EA] |
| | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] |
| | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | [a] Parapane [AF] | [a] PHARMACY CARE PARACETAMOL [SI] |
| | | | | | [a] Wagner Health Paracetamol [BG] | |

### PARACETAMOL

**Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**paracetamol 665 mg modified release tablet, 96**

| 10598T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | .. | *20.51 | 7.30 | [a] CHEMISTS' OWN OSTEO RELIEF PARACETAMOL [RF]<br>[a] Pharmacy Action Paracetamol Osteo 665 [GQ] | [a] Osteomol 665 Paracetamol [CR] |

## ▪ PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**paracetamol 500 mg tablet, 100**

| 10585D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 4 | .. | *18.00 | 7.30 | [a] APO-Paracetamol [TX]<br>[a] Panamax [SW]<br>[a] Paracetamol Sandoz Pharma [QS]<br>[a] Parapane [AF]<br>[a] Wagner Health Paracetamol [BG] | [a] Febridol [EA]<br>[a] Paracetamol (Sandoz) [SZ]<br>[a] Paralgin [OW]<br>[a] PHARMACY CARE PARACETAMOL [SI] |

*Gabapentinoids*

## ▪ GABAPENTIN

**Authority required**

Refractory neuropathic pain

**Clinical criteria:**

- The condition must be unable to be controlled by other drugs.

**gabapentin 100 mg capsule, 100**

| 4591P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 17.16 | 7.30 | [a] APX-Gabapentin [GX]<br>[a] Gabapentin APOTEX [TY]<br>[a] Nupentin 100 [AF] | [a] Gabacor [CR]<br>[a] Neurontin [UJ] |

**gabapentin 300 mg capsule, 100**

| 4592Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 24.48 | 7.30 | [a] APX-Gabapentin [GX]<br>[a] Gabapentin APOTEX [TY]<br>[a] Gabapentin Sandoz [SZ]<br>[a] Nupentin 300 [AF] | [a] Gabacor [CR]<br>[a] Gabapentin generichealth [HQ]<br>[a] Neurontin [UJ] |

**gabapentin 400 mg capsule, 100**

| 4593R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 28.66 | 7.30 | [a] APX-Gabapentin [GX]<br>[a] Gabapentin APOTEX [TY]<br>[a] Gabapentin Sandoz [SZ]<br>[a] Nupentin 400 [AF] | [a] Gabacor [CR]<br>[a] Gabapentin generichealth [HQ]<br>[a] Neurontin [UJ] |

**gabapentin 600 mg tablet, 100**

| 4594T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 37.85 | 7.30 | [a] Gabapentin AN [EA]<br>[a] Neurontin [UJ] | [a] Gabapentin APOTEX [TY]<br>[a] Pharmacor Gabapentin 600 [CR] |

**gabapentin 800 mg tablet, 100**

| 4595W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | .. | 46.14 | 7.30 | [a] Gabapentin APOTEX [TY]<br>[a] Pharmacor Gabapentin 800 [CR] | [a] Neurontin [UJ] |

# ▪ PSYCHOLEPTICS

## ANXIOLYTICS

*Benzodiazepine derivatives*

## ▪ BROMAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**

RPBS

Terminal disease

**Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**

Refractory phobic or anxiety states

**Clinical criteria:**

- The treatment must be for the short-term.

**bromazepam 3 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4150K | 2 | .. | .. | *33.05 | 7.30 | Lexotan [PB] |

**bromazepam 6 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4151L | 2 | .. | .. | *38.79 | 7.30 | Lexotan [PB] |

## HYPNOTICS AND SEDATIVES

*Benzodiazepine derivatives*

### ▪ FLUNITRAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Terminal disease

**Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**

Refractory phobic or anxiety states

**Clinical criteria:**

- The treatment must be for the short-term.

**flunitrazepam 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4216X | 1 | .. | .. | 23.23 | 7.30 | Hypnodorm [AF] |

*Benzodiazepine related drugs*

### ▪ ZOPICLONE

**Restricted benefit**

Insomnia

**Clinical criteria:**

- The treatment must be for the short-term.

**zopiclone 7.5 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13307J | 1 | 1 | .. | 20.37 | 7.30 | Imovane [SW] |

**zopiclone 7.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 4522B | 1 | .. | .. | 26.33 | 7.30 | [a] APO-Zopiclone [TX]<br>[a] Imrest [AF]<br>[a] Zopiclone GH [GQ] | [a] Imoclone [RW]<br>[a] Pharmacor Zopiclone [CR] |
| | | | .. | 29.07 | 7.30 | [a] Imovane [SW] | |

# ▪ OTHER NERVOUS SYSTEM DRUGS

## DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in nicotine dependence*

### ▪ NICOTINE

**Note** Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

**Authority required**

Nicotine dependence

**Clinical criteria:**

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

**nicotine 14 mg/24 hours patch, 7**

| 4572P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *56.63 | 7.30 | QuitX [AF] |

**nicotine 21 mg/24 hours patch, 7**

| 4573Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | .. | *59.59 | 7.30 | QuitX [AF] |

**nicotine 7 mg/24 hours patch, 7**

| 4571N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | .. | .. | *53.47 | 7.30 | QuitX [AF] |

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ANTHELMINTICS

### ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

### MEBENDAZOLE

**Note** Pharmaceutical benefits that have the forms mebendazole 100 mg tablet and mebendazole 100 mg chewable tablet are equivalent for the purposes of substitution.

**mebendazole 100 mg chewable tablet, 6**

| 12194T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 19.19 | 7.30 | [a] Trust Deworm [CR] |

**mebendazole 100 mg tablet, 6**

| 4325P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | .. | .. | 19.19 | 7.30 | [a] Pharmacy Action Worm Treatment [GQ] |

# RESPIRATORY SYSTEM

## NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Sympathomimetics, plain*

### OXYMETAZOLINE

**oxymetazoline hydrochloride 0.05% nasal spray, 20 mL**

| 11711J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 21.98 | 7.30 | [a] Pharmacy Action Nasal Decongestant [GQ] | [a] Trust Decongestant Nasal Spray [CR] |

**oxymetazoline hydrochloride 0.05% nasal spray, 15 mL**

| 4378K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 22.32 | 7.30 | Drixine [BN] |

**oxymetazoline hydrochloride 0.05% nasal spray, 18 mL**

| 4379L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 21.98 | 7.30 | Logicin Rapid Relief [AS] |

*Antiallergic agents, excl. corticosteroids*

### CROMOGLYCATE

**sodium cromoglycate 2% nasal spray, 26 mL**

| 4468E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | .. | 27.33 | 7.30 | Rynacrom [SW] |

*Corticosteroids*

### BUDESONIDE

**Restricted benefit**

Severe intractable rhinitis

**budesonide 64 microgram/actuation nasal spray, 120 actuations**

| 4092J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 43.58 | 7.30 | Budamax Aqueous [JT] |

## NASAL DECONGESTANTS FOR SYSTEMIC USE

*Sympathomimetics*

### ▪ PSEUDOEPHEDRINE

**pseudoephedrine hydrochloride 60 mg tablet, 12**

| 4029C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | .. | .. | 16.52 | 7.30 | [a] Pharmacy Action Sinus & Nasal Decongestant Relief [GQ] | [a] Trust Sinus & Nasal Decongestant [CR] |

# ▪ ANTIHISTAMINES FOR SYSTEMIC USE

## ANTIHISTAMINES FOR SYSTEMIC USE

*Piperazine derivatives*

### ▪ CETIRIZINE

**cetirizine hydrochloride 10 mg tablet, 30**

| 4175R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | .. | .. | 29.96 | 7.30 | [a] Pharmacy Action Cetrelief [GQ] | [a] Trust Cetirizine [CR] |
| | | | .. | 33.19 | 7.30 | [a] Alzene [AF] | |

*Other antihistamines for systemic use*

### ▪ FEXOFENADINE

**fexofenadine hydrochloride 120 mg tablet, 30**

| 4238C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | .. | .. | 29.78 | 7.30 | [a] Pharmacy Action Fexorelief 120 [GQ] | [a] Trust Fexit 120 [CR] |
| | | | .. | 32.99 | 7.30 | [a] Xergic [AF] | |
| | | | .. | 49.20 | 7.30 | [a] Telfast 120 [SW] | |

**fexofenadine hydrochloride 60 mg tablet, 20**

| 4237B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | .. | .. | *57.06 | 7.30 | Telfast [SW] |

### ▪ LORATADINE

**loratadine 10 mg tablet, 30**

| 4313B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | .. | .. | 32.39 | 7.30 | [a] Pharmacy Action Lorastyne [GQ]<br>[a] Trust Loratadine Antihistamine [RM] | [a] Trust Loratadine [CR] |
| | | | .. | 36.09 | 7.30 | [a] Allereze [AF] | |
| | | | .. | 45.72 | 7.30 | [a] Lorano [SZ] | |
| | | | .. | 47.99 | 7.30 | [a] Claratyne [BN] | |

# ▪ SENSORY ORGANS

# ▪ OTOLOGICALS

## OTHER OTOLOGICALS

*Indifferent preparations*

### ▪ CARBAMIDE PEROXIDE

**carbamide peroxide 6.5% ear drops, 12 mL**

| 4176T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 22.47 | 7.30 | Ear Clear for Ear Wax Removal [KY] |

### ▪ DOCUSATE

**docusate sodium 0.5% ear drops, 10 mL**

| 4199B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 19.99 | 7.30 | Waxsol [GO] |

### ▪ ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL

**ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% ear drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4180B | ‡1 | .. | .. | 19.65 | 7.30 | Cerumol [UN] |

# ▪ VARIOUS

## ▪ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

### ▪ SODIUM POLYSTYRENE SULFONATE

**sodium polystyrene sulfonate 999.3 mg/g powder, 454 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4470G | ‡1 | 2 | .. | 82.68 | 7.30 | Resonium-A [SW] |

## ▪ GENERAL NUTRIENTS

### OTHER NUTRIENTS

*Other combinations of nutrients*

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C AND E

**Restricted benefit**

Stage 2 and above pressure injury

**Clinical criteria:**

- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10850C | 4 | 5 | .. | *162.89 | 7.30 | Arginaid [NT] |

### ▪ PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

**Restricted benefit**

Stage 2 and above pressure injury

**Clinical criteria:**

- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 200 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11401C | 2 | 5 | .. | *206.87 | 7.30 | Cubitan [SB] |

**protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 237 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13020G | 2 | 5 | .. | *241.01 | 7.30 | Arginaid Extra [NT] |

## ▪ ALL OTHER NON-THERAPEUTIC PRODUCTS

### ALL OTHER NON-THERAPEUTIC PRODUCTS

### ▪ LUBRICATING AGENT

**lubricating agent gel, 100 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4306P | 1 | .. | .. | 16.40 | 7.30 | Lubri-Gel [PP] |

*Other non-therapeutic auxiliary products*

### ▪ BANDAGE ABSORBENT WOOL

**bandage absorbent wool 10 cm x 3 m bandage, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4653X | 1 | .. | .. | 25.08 | 7.30 | Surepress 650948 [CC] |

## ▪ BANDAGE CALICO

**bandage calico large triangular bandage, 1**

4717G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 19.00 | 7.30 | Handy 36361414 [BV] |

## ▪ BANDAGE COMPRESSION

**bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack**

11714M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 39.58 | 7.30 | Rosidal TCS 26484 [LC] |

## ▪ BANDAGE COMPRESSION

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**bandage compression two layer bandage, 1**

12592R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 52.68 | 7.30 | Putter Pro 2 931685 [HR] |

## ▪ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**bandage compression 10 cm x 3 m high stretch bandage, 1**

4748X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *73.42 | 7.30 | Surepress 650947 [CC] |
| | | .. | *153.67 | 7.30 | Tensopress 71723-00 [BV] |

**bandage compression 8 cm x 2.6 m short stretch bandage, 1**

4654Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *78.77 | 7.30 | Comprilan 01027-00 [BV] |

## ▪ BANDAGE COMPRESSION

**Note** Use with caution if arterial disease present and avoid if severe arterial disease.
**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**bandage compression 25 cm to 32 cm two layer bandage, 1**

13010R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 47.99 | 7.30 | UrgoK2 100397 [UG] |

**bandage compression 25 cm to 32 cm two layer bandage, 1**

13016C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 47.99 | 7.30 | UrgoK2 Lite 100401 [UG] |

**bandage compression 18 cm to 25 cm two layer bandage, 1**

13005L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 42.17 | 7.30 | UrgoK2 100396 [UG] |

**bandage compression 18 cm to 25 cm two layer bandage, 1**

13006M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | .. | 42.17 | 7.30 | UrgoK2 Lite 100400 [UG] |

## ▪ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.
**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage compression four layer bandage, 1**

4598B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *197.82 | 7.30 | Profore Lite 66050415 [SN] |

**bandage compression four layer bandage, 1**

4658E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *295.42 | 7.30 | Profore 66050016 [SN] |

## ▪ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

### bandage compression 10 cm x 3.5 m high stretch bandage, 1

4657D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *78.57 | 7.30 | Setopress 3505 [MH] |

## ▪ BANDAGE COMPRESSION

**Note** Use with caution if arterial disease present and avoid if severe arterial disease.

**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**Restricted benefit**

Venous ulcer

Treatment Phase: Initial treatment

**Restricted benefit**

Venous ulcer

Treatment Phase: Continuing treatment

### bandage compression two layer bandage, 1

4050E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 44.75 | 7.30 | Coban 2 [MM] |

## ▪ BANDAGE RETENTION COHESIVE HEAVY

### bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1

4813H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *25.73 | 7.30 | Peg 7423 [MM] |

### bandage retention cohesive heavy 10 cm x 2 m bandage, 1

4660G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *24.25 | 7.30 | Coban 1584 [MM] |

### bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1

4814J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *31.91 | 7.30 | Peg 7425 [MM] |

### bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1

4811F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *19.59 | 7.30 | Peg 7420 [MM] |

### bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1

4812G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *22.45 | 7.30 | Peg 7422 [MM] |

## ▪ BANDAGE RETENTION COHESIVE LIGHT

### bandage retention cohesive light 10 cm x 2 m bandage, 1

4662J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *35.37 | 7.30 | Handygauze Cohesive 8635 [BV] |

### bandage retention cohesive light 6 cm x 2 m bandage, 1

4719J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *21.51 | 7.30 | Handygauze Cohesive 8633 [BV] |

### bandage retention cohesive light 2.5 cm x 2 m bandage, 2

4718H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 19.13 | 7.30 | Handygauze Cohesive 8631 [BV] |

## ▪ BANDAGE RETENTION COTTON CREPE

### bandage retention cotton crepe 10 cm x 2.3 m bandage, 1

4729X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *29.47 | 7.30 | Telfa 8254F [KE] |
| | | .. | *34.91 | 7.30 | Tensocrepe 36301001 [BV] |

RPBS

**bandage retention cotton crepe 5 cm x 2.3 m bandage, 1**

4727T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *22.55 | 7.30 | Telfa 8252F [KE] |
| | | .. | *25.21 | 7.30 | Tensocrepe 36300501 [BV] |

**bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

4728W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *26.73 | 7.30 | Telfa 8253F [KE] |
| | | .. | *29.77 | 7.30 | Tensocrepe 36307501 [BV] |

## ▪ BANDAGE TUBULAR

**bandage tubular size C (15 cm to 25 cm) straight bandage, 1**

4663K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.79 | 7.30 | Elastoplast 2225 [BE] |

**bandage tubular size D (25 cm to 43 cm) straight bandage, 1**

4664L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.79 | 7.30 | Elastoplast 2226 [BE] |

**bandage tubular size E (35 cm to 45 cm) straight bandage, 1**

4665M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.79 | 7.30 | Elastoplast 2227 [BE] |

## ▪ BANDAGE TUBULAR

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular 10 cm x 1 m bandage, 1**

4859R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.43 | 7.30 | Tubigrip F 1548 [MH] |

**bandage tubular 6.25 cm x 1 m bandage, 1**

4855M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.43 | 7.30 | Tubigrip B 1520 [MH] |

**bandage tubular 6.75 cm x 1 m bandage, 1**

4856N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.43 | 7.30 | Tubigrip C 1545 [MH] |

**bandage tubular 7.5 cm x 1 m bandage, 1**

4857P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.43 | 7.30 | Tubigrip D 1546 [MH] |

**bandage tubular 8.75 cm x 1 m bandage, 1**

4858Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.43 | 7.30 | Tubigrip E 1547 [MH] |

## ▪ BANDAGE TUBULAR FINGER

**BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1**

4798M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 22.86 | 7.30 | Tubegauz 0501633 [SS] |

## ▪ BANDAGE TUBULAR LIGHT WEIGHT

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular light weight 10 m large limb size bandage, 1**

4673Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 31.87 | 7.30 | Tubifast 2438 [MH] |

**bandage tubular light weight 10 m medium limb size bandage, 1**

4672X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 30.64 | 7.30 | Tubifast 2436 [MH] |

**bandage tubular light weight 10 m small limb size bandage, 1**

4671W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 27.20 | 7.30 | Tubifast 2434 [MH] |

## ▪ BANDAGE TUBULAR LONG STOCKING

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular long stocking large size bandage, 1**

4799N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *39.69 | 7.30 | Tubigrip 1484 [MH] |

**bandage tubular long stocking medium size bandage, 1**

4797L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *39.69 | 7.30 | Tubigrip 1483 [MH] |

**bandage tubular long stocking small size bandage, 1**

4674B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *39.69 | 7.30 | Tubigrip 1482 [MH] |

**bandage tubular long stocking XX/large size bandage, 1**

4675C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *39.71 | 7.30 | Tubigrip 1486 [MH] |

## ▪ BANDAGE TUBULAR SHORT STOCKING

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage tubular short stocking large D/E size bandage, 1**

4816L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *29.47 | 7.30 | Tubigrip 1481 [MH] |

**bandage tubular short stocking medium C/D size bandage, 1**

4815K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *29.47 | 7.30 | Tubigrip 1480 [MH] |

**bandage tubular short stocking small B/C size bandage, 1**

4661H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *29.47 | 7.30 | Tubigrip 1479 [MH] |

## ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

4669R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *33.19 | 7.30 | Steripaste 3610 [MH] |

## ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

4750B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | .. | *98.21 | 7.30 | Viscopaste 4948 [SN] |

**bandage zinc paste 80 cm (stockings) bandage, 4**

4760M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 112.52 | 7.30 | ZipZoc 66000747 [SN] |

## ▪ BETAINE + POLYAMINOPROPYL BIGUANIDE

**betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules**

2525X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 30.60 | 7.30 | Prontosan Wound Irrigation Solution [BR] |

## ▪ CADEXOMER-IODINE

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet**

4936T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 192.33 | 7.30 | Iodosorb 66051340 [SN] |

**cadexomer-iodine 3 g powder, 7 sachets**

4931M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 88.36 | 7.30 | Iodosorb Powder 66051070 [SN] |

**cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet**

4937W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 202.69 | 7.30 | Iodosorb 66051360 [SN] |

**cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet**

4935R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 132.90 | 7.30 | Iodosorb 66051330 [SN] |

**cadexomer-iodine 50% ointment, 4 x 10 g**

4932N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 140.68 | 7.30 | Iodosorb Ointment 66051240 [SN] |

**cadexomer-iodine 50% ointment, 2 x 20 g**

4933P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 139.35 | 7.30 | Iodosorb Ointment 66051230 [SN] |

## ▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

**dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1**

4681J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *98.87 | 7.30 | Actisorb Plus MAP105 [KI] |

**dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10**

4742N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 78.95 | 7.30 | CarboFLEX 403202 [CC] |

**dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5**

4743P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 88.85 | 7.30 | CarboFLEX 403204 [CC] |

## ▪ DRESSING ALGINATE CAVITY WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**dressing alginate cavity wound 2 g rope, 1**

4832H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *106.37 | 7.30 | Sorbsan 1411 [UM] |

**dressing alginate cavity wound 2 g rope, 5 x 2 g**

1905G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *111.93 | 7.30 | Kaltostat 168117 [CC] |

## ▪ DRESSING ALGINATE CAVITY WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

4682K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *133.31 | 7.30 | Comfeel SeaSorb Filler 3740 [CT] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

### dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

4683L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 89.95 | 7.30 | Kaltostat 168212 [CC] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing alginate superficial wound 5 cm x 5 cm dressing, 10

4699H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 51.47 | 7.30 | Kaltostat 168210 [CC] |
| | | .. | 69.09 | 7.30 | Algisite M 66000519 [SN] |

### dressing alginate superficial wound 10 cm x 10 cm dressing, 10

4700J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 130.05 | 7.30 | Algisite M 66000520 [SN] |

### dressing alginate superficial wound 15 cm x 20 cm dressing, 10

4691X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 316.89 | 7.30 | Algisite M 66000521 [SN] |

## ▪ DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### dressing alginate superficial wound 5 cm x 5 cm dressing, 1

4684M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 1 | .. | *48.97 | 7.30 | Comfeel SeaSorb Dressing 3705 [CT] |

### dressing alginate superficial wound 10 cm x 10 cm dressing, 1

4831G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 1 | .. | *83.87 | 7.30 | Sorbsan 1410 [UM] |
| | | .. | *89.07 | 7.30 | Comfeel SeaSorb Dressing 3710 [CT] |

## ▪ DRESSING ALGINATE WITH MANUKA HONEY

**Note** Suitable for yellow sloughy infected and malodorous wounds.

### dressing alginate with manuka honey 10 cm x 10 cm dressing, 5

10849B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 4 | .. | 71.05 | 7.30 | Algivon Plus CR4225 [DJ] |

**dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5**

| 10857K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 4 | .. | 82.75 | 7.30 | Algivon Plus Ribbon & Probe CR4231 [DJ] |

## ▪ DRESSING ALGINATE WITH SILVER CAVITY WOUND

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing alginate with silver cavity wound 3 cm x 44 cm dressing, 10**

| 12765W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 401.09 | 7.30 | Melgisorb Ag 256605 [MH] |

## ▪ DRESSING ALGINATE WITH SILVER DEEP WOUND

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing alginate with silver deep wound 5 cm x 5 cm dressing, 10**

| 12772F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 136.35 | 7.30 | Melgisorb Ag 256055 [MH] |

**dressing alginate with silver deep wound 10 cm x 10 cm dressing, 10**

| 12801R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 236.94 | 7.30 | Melgisorb Ag 256105 [MH] |

## ▪ DRESSING CONTACT LAYER LIPIDOCOLLOID

**dressing contact layer lipidocolloid 10 cm x 10 cm dressing, 10**

| 13022J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 1 | .. | 71.14 | 7.30 | UrgoTul Contact 100351 [UG] |

## ▪ DRESSING CONTACT LAYER LIPIDOCOLLOID WITH SUCROSE OCTASULFATE

**dressing contact layer lipidocolloid with sucrose octasulfate 10 cm x 10 cm dressing, 10**

| 13002H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 125.40 | 7.30 | UrgoStart Contact-Interface-Tul 100380 [UG] |

**dressing contact layer lipidocolloid with sucrose octasulfate 15 cm x 20 cm dressing, 10**

| 13011T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 229.08 | 7.30 | UrgoStart Contact-Interface-Tul 100381 [UG] |

## ▪ DRESSING FILM

**dressing film 15 cm x 20 cm dressing, 1**

| 4688R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | .. | .. | *34.05 | 7.30 | Tegaderm Transparent 1628 [MM] |

**dressing film 10 cm x 12 cm dressing, 4**

| 4687Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 24.49 | 7.30 | Nexcare Tegaderm Transparent H1626 [MM] |

**dressing film 6 cm x 7 cm dressing, 8**

| 4686P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 21.01 | 7.30 | Nexcare Tegaderm Transparent H1624 [MM] |

## ▪ DRESSING FILM

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film 10 cm x 12 cm dressing, 10**

4893M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 44.07 | 7.30 | Op-Site Flexigrid 4629 [SN] |

## ▪ DRESSING FILM ISLAND

**dressing film island 5 cm x 7 cm dressing, 1**

4689T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *21.47 | 7.30 | Tegaderm Transparent Island 3582 [MM] |

**dressing film island 9 cm x 10 cm dressing, 1**

4690W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *31.47 | 7.30 | Tegaderm Transparent Island 3586 [MM] |

## ▪ DRESSING FILM ISLAND

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing film island 5 cm x 7.2 cm dressing, 5**

4898T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *35.63 | 7.30 | Cutifilm Plus 36361370 [SN] |

**dressing film island 8 cm x 10 cm dressing, 5**

4899W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *53.05 | 7.30 | Cutifilm Plus 36361371 [SN] |

## ▪ DRESSING FOAM HEAVY EXUDATE

**Restricted benefit**

Wounds

**Clinical criteria:**

- Patient must have a wound with highly viscous exudate.

**dressing foam heavy exudate 5 cm x 5 cm dressing, 5**

12797M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 37.77 | 7.30 | Mepilex XT 211015 [MH] |

**dressing foam heavy exudate 10 cm x 10 cm dressing, 5**

12760N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 43.79 | 7.30 | Mepilex XT 211100 [MH] |

**dressing foam heavy exudate 20 cm x 20 cm dressing, 5**

12776K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 131.39 | 7.30 | Mepilex XT 211400 [MH] |

## ▪ DRESSING FOAM HEAVY EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam heavy exudate 10 cm x 10 cm dressing, 10**

4795J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 164.17 | 7.30 | Allevyn 66007637 [SN] |

## ▪ DRESSING FOAM LIPIDOCOLLOID WITH SILICONE HEAVY EXUDATE

**dressing foam lipidocolloid with silicone heavy exudate 10 cm x 10 cm dressing, 10**

13007N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 94.47 | 7.30 | UrgoTul Absorb Silicone Border 102203 [UG] |

## ▪ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE

**dressing foam lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10**

13023K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 128.49 | 7.30 | UrgoStart Border 100480 [UG] |

**dressing foam lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10**

13017D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 166.06 | 7.30 | UrgoStart Border 100481 [UG] |

**dressing foam lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10**

13021H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 363.16 | 7.30 | UrgoStart Border 100482 [UG] |

## ▪ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

**dressing foam lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10**

13008P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 138.61 | 7.30 | UrgoStart Pad 100376 [UG] |

**dressing foam lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10**

13003J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 301.52 | 7.30 | UrgoStart Pad 100377 [UG] |

**dressing foam lipidocolloid with sucrose octasulfate moderate exudate 12 cm x 19 cm dressing, 10**

13004K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 225.72 | 7.30 | UrgoStart Pad 100378 [UG] |

## ▪ DRESSING FOAM MODERATE EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate cavity conforming foam, 20 g sachet**

4694C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | .. | 100.82 | 7.30 | Cavicare 4563 [SN] |

## ▪ DRESSING FOAM MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10**

4590N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 162.98 | 7.30 | Allevyn Adhesive 66000044 [SN] |

## ▪ DRESSING FOAM WITH SILICONE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10**

10017F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 69.04 | 7.30 | Allevyn Life 66801067 [SN] |

**dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10**

10029W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 97.10 | 7.30 | Allevyn Life 66801068 [SN] |

**dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10**

10023M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 133.85 | 7.30 | Allevyn Life 66801069 [SN] |

**dressing foam with silicone 21 cm x 21 cm dressing, 10**

| 10021K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 269.36 | 7.30 | Allevyn Life 66801070 [SN] |

**dressing foam with silicone 10.5 cm x 10.5 cm dressing, 10**

| 11384E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 69.04 | 7.30 | Allevyn Life Non-Bordered 66801748 [SN] |

**dressing foam with silicone 16 cm x 16 cm dressing, 10**

| 11393P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 117.91 | 7.30 | Allevyn Life Non-Bordered 66801749 [SN] |

## ▪ DRESSING FOAM WITH SILICONE AND SILVER

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

| 2439J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 106.52 | 7.30 | Mepilex Ag [MH] |

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

| 2470B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 113.60 | 7.30 | Mepilex Border Ag [MH] |

## ▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

| 12206K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 72.02 | 7.30 | Mepilex Border Flex 595311 [MH] |

**dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10**

| 12184G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 53.96 | 7.30 | Mepilex Border Flex 595211 [MH] |

**dressing foam with silicone heavy exudate 15 cm x 20 cm dressing, 10**

| 12185H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 178.92 | 7.30 | Mepilex Border Flex 595611 [MH] |

**dressing foam with silicone heavy exudate 22 cm x 23 cm dressing, 6**

| 12195W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 168.52 | 7.30 | Mepilex Border Heel 282750 [MH] |

**dressing foam with silicone heavy exudate 16 cm x 20 cm dressing, 5**

| 12216Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 85.08 | 7.30 | Mepilex Border Sacrum 282050 [MH] |

**dressing foam with silicone heavy exudate 22 cm x 25 cm dressing, 5**

| 12207L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 128.79 | 7.30 | Mepilex Border Sacrum 282450 [MH] |

## ▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

4196W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 87.13 | 7.30 | Allevyn Gentle 66800248 [SN] |

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

4230P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 91.59 | 7.30 | Allevyn Gentle Border 66800270 [SN] |

**dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10**

4207K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 65.40 | 7.30 | Allevyn Gentle Border 66800269 [SN] |

## ▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

**dressing foam with silicone light exudate 4 cm x 5 cm dressing, 10**

12780P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 30.41 | 7.30 | Mepilex Border Lite 281000 [MH] |

**dressing foam with silicone light exudate 5 cm x 12.5 cm dressing, 5**

12774H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 32.99 | 7.30 | Mepilex Border Lite 281100 [MH] |

**dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5**

12804X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 39.98 | 7.30 | Mepilex Border Lite 281300 [MH] |

## ▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5**

4645L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 40.63 | 7.30 | Mepilex Lite 284100 [MH] |

**dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5**

4644K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 31.81 | 7.30 | Mepilex Lite 284000 [MH] |

## ▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

**dressing foam with silicone moderate exudate 5 cm x 12.5 cm dressing, 5**

12782R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 31.27 | 7.30 | Mepilex Border Flex Lite 581100 [MH] |

**dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5**

12799P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 37.88 | 7.30 | Mepilex Border Flex Lite 581300 [MH] |

**dressing foam with silicone moderate exudate 4 cm x 5 cm dressing, 10**

12777L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 28.58 | 7.30 | Mepilex Border Flex Lite 581011 [MH] |

## ▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5**

4626L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 44.75 | 7.30 | Mepilex 294100 [MH] |

## ▪ DRESSING FOAM WITH SILVER

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

4252T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 167.71 | 7.30 | Allevyn Ag Adhesive 66800073 [SN] |

**dressing foam with silver 7.5 cm x 7.5 cm dressing, 10**

4263J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 167.71 | 7.30 | Allevyn Ag Gentle Border 66800460 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4255Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 249.34 | 7.30 | Allevyn Ag Adhesive 66800075 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4259E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 254.13 | 7.30 | Allevyn Ag Non-Adhesive 66800086 [SN] |

**dressing foam with silver 10 cm x 10 cm dressing, 10**

4266M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 249.34 | 7.30 | Allevyn Ag Gentle Border 66800461 [SN] |

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

4258D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 309.70 | 7.30 | Allevyn Ag Adhesive 66800078 [SN] |

**dressing foam with silver 12.5 cm x 12.5 cm dressing, 10**

4270R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 309.70 | 7.30 | Allevyn Ag Gentle Border 66800462 [SN] |

## ▪ DRESSING GAUZE

**dressing gauze eye pad, 12 pads**

4768Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 18.58 | 7.30 | Curity 4112 [KE] |

## ▪ DRESSING GAUZE ABSORBENT

**dressing gauze absorbent 10 cm x 10 cm pad, 100**

4708T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 34.32 | 7.30 | Handy 71117-06 [BV] |

**dressing gauze absorbent 5 cm x 5 cm pad, 100**

4707R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.59 | 7.30 | Handy 71117-05 [BV] |

## ▪ DRESSING GAUZE PARAFFIN

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing gauze paraffin 10 cm x 10 cm dressing, 10**

4759L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 29.33 | 7.30 | Jelonet 7404 [SN] |

## ▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

4845B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 37.36 | 7.30 | Bactigras 7457 [SN] |

## ▪ DRESSING GELLING FIBRE

### dressing gelling fibre 5 cm x 5 cm dressing, 10

12187K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 41.70 | 7.30 | Exufiber 709900 [MH] |

### dressing gelling fibre 15 cm x 15 cm dressing, 10

12202F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 159.38 | 7.30 | Exufiber 709903 [MH] |

### dressing gelling fibre 1 cm x 45 cm dressing, 5

12213T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 52.99 | 7.30 | Exufiber 709908 [MH] |

### dressing gelling fibre 2 cm x 45 cm dressing, 5

12182E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 52.99 | 7.30 | Exufiber 709909 [MH] |

### dressing gelling fibre 10 cm x 10 cm dressing, 10

12181D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 76.10 | 7.30 | Exufiber 709901 [MH] |

## ▪ DRESSING GELLING FIBRE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing gelling fibre 10 cm x 10 cm dressing, 10

2486W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 118.09 | 7.30 | Durafiber 66800560 [SN] |

### dressing gelling fibre 15 cm x 15 cm dressing, 5

2445Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *245.73 | 7.30 | Durafiber 66800561 [SN] |

### dressing gelling fibre 2 cm x 45 cm rope, 5

2462N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 101.64 | 7.30 | Durafiber 66800563 [SN] |

## ▪ DRESSING GELLING FIBRE LIPIDOCOLLOID

### dressing gelling fibre lipidocolloid 15 cm x 20 cm dressing, 10

13009Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 233.78 | 7.30 | UrgoClean Pad 100372 [UG] |

### dressing gelling fibre lipidocolloid 10 cm x 10 cm dressing, 10

13015B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 105.99 | 7.30 | UrgoClean Pad 100370 [UG] |

## ▪ DRESSING HYDROACTIVE DEBRIDEMENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### dressing hydroactive debridement 4 cm dressing, 10

12636C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 92.91 | 7.30 | HydroClean Plus Cavity 609622 [HR] |

**dressing hydroactive debridement 4 cm dressing, 10**

12637D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 89.08 | 7.30 | HydroClean Plus 609602 [HR] |

**dressing hydroactive debridement 4 cm dressing, 10**

4949L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 84.32 | 7.30 | TenderWet 24 Active 609210 [HR] |

**dressing hydroactive debridement 5.5 cm dressing, 10**

12629Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 148.12 | 7.30 | HydroClean Plus 609606 [HR] |

**dressing hydroactive debridement 5.5 cm dressing, 10**

4948K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 86.18 | 7.30 | TenderWet Active Cavity 609272 [HR] |

**dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10**

12660H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 197.17 | 7.30 | HydroClean Plus 609608 [HR] |

**dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10**

4950M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 111.92 | 7.30 | TenderWet 24 Active 609213 [HR] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings**

4695D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 108.28 | 7.30 | Tielle MTL101E [KI] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings**

4696E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 131.52 | 7.30 | Tielle MTL103 [KI] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10**

4927H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 87.09 | 7.30 | Biatain Non-adhesive 3410 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5**

4928J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 85.74 | 7.30 | Biatain Non-adhesive 3413 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10**

4929K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 95.29 | 7.30 | Biatain Adhesive 3420 [CT] |

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5**

4930L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 2 | .. | 92.44 | 7.30 | Biatain Adhesive 3423 [CT] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10**

4905E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 78.27 | 7.30 | Allevyn Thin 66047576 [SN] |

**dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5**

4906F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *140.41 | 7.30 | Allevyn Thin 66047578 [SN] |

## ▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

4886E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *100.01 | 7.30 | Cutinova Hydro 66047443 [SN] |

**dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10**

4885D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 61.47 | 7.30 | Cutinova Hydro 66047441 [SN] |

## ▪ DRESSING HYDROCOLLOID CAVITY WOUND

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressing hydrocolloid cavity wound paste, 30 g**

4896Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | .. | .. | *140.37 | 7.30 | DuoDERM Paste 187930 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4907G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 72.35 | 7.30 | DuoDERM Extra Thin 187955 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4924E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 70.59 | 7.30 | Comfeel Plus Transparent 3533 [CT] |

**dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10**

4888G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 43.79 | 7.30 | Comfeel Plus Transparent 3530 [CT] |

**dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10**

4889H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 83.99 | 7.30 | Comfeel Plus Transparent 3536 [CT] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4947J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 50.22 | 7.30 | Hydrocoll Thin 900758 [HR] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

4897R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *81.15 | 7.30 | DuoDERM CGF 187660 [CC] |

**dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5**

4920Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *215.79 | 7.30 | DuoDERM CGF 187662 [CC] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

4921B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 106.35 | 7.30 | Replicare Ultra 66000434 [SN] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

4945G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 50.22 | 7.30 | Hydrocoll 900744 [HR] |

**dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10**

4946H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 88.89 | 7.30 | Hydrocoll 900936 [HR] |

## ▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1**

4678F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *57.22 | 7.30 | Comfeel Plus Pressure Relieving 3350 [CT] |

**DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1**

4923D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 81.70 | 7.30 | Comfeel Plus Ulcer Dressing 3110 [CT] |

**dressing hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1**

4679G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | .. | .. | *61.32 | 7.30 | Comfeel Plus Pressure Relieving 3353 [CT] |

## ▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

### dressing hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10

10832D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 118.91 | 7.30 | Aquacel Foam Adhesive [CC] |

### dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

10837J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 122.56 | 7.30 | Aquacel Foam Non-Adhesive [CC] |

### dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

2797F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 98.95 | 7.30 | Aquacel Extra 420672 [CC] |

### dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5

2803M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 1 | .. | *201.49 | 7.30 | Aquacel Extra 420673 [CC] |

### dressing hydrofibre alternate to alginates 2 cm x 45 cm ribbon, 5

4698G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 83.25 | 7.30 | Aquacel 403770 [CC] |

## ▪ DRESSING HYDROFIBRE WITH SILVER

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

10098L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 275.41 | 7.30 | Aquacel Ag 403710 [CC] |

### dressing hydrofibre with silver 2 cm x 45 cm ribbon, 5

10105W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 218.01 | 7.30 | Aquacel Ag 403771 [CC] |

### dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

10097K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 257.51 | 7.30 | Aquacel Ag 403708 [CC] |

## ▪ DRESSING HYDROGEL

### dressing hydrogel 7.5 cm x 15 cm dressing, 10

11395R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 115.24 | 7.30 | Sorbact Gel Dressing S98137 [BV] |

### dressing hydrogel 10 cm x 10 cm dressing, 5

11709G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 31.54 | 7.30 | Suprasorb G 33631 [LC] |

### dressing hydrogel 10 cm x 10 cm dressing, 20

2471C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 186.36 | 7.30 | Sorbact Absorption Dressing S98222 [BV] |

## ▪ DRESSING HYDROGEL

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### dressing hydrogel 12.5 cm x 12.5 cm dressing, 5

12659G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 43.20 | 7.30 | Hydrosorb Comfort 900723 [HR] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

### dressing hydrogel amorphous gel, 50 g

4914P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *36.21 | 7.30 | Solugel 10336 [JJ] |

### dressing hydrogel amorphous gel, 3 x 30 g

4913N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 1 | .. | *95.43 | 7.30 | DuoDERM Gel H7987 [CC] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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### dressing hydrogel amorphous gel, 10 x 15 g

4912M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 65.77 | 7.30 | DuoDERM Gel 187990 [CC] |
| | | .. | 72.69 | 7.30 | Comfeel Purilon Gel 3900 [CT] |

## ▪ DRESSING HYDROGEL AMORPHOUS

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing hydrogel amorphous gel, 25 g

4894N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 3 | .. | *83.53 | 7.30 | Intrasite Gel 7313 [SN] |

### dressing hydrogel amorphous gel, 50 g

4599C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 3 | .. | *40.92 | 7.30 | SoloSite Gel 36361338 [SN] |

## ▪ DRESSING HYDROGEL FOAM

### dressing hydrogel foam 10 cm x 10 cm dressing, 10

2533H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 126.54 | 7.30 | Sorbact Foam Dressing S98310 [BV] |

## ▪ DRESSING HYDROGEL RIBBON

### dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

2512F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 188.62 | 7.30 | Sorbact Ribbon Gauze S98118 [BV] |

### dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

2529D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | .. | .. | 186.36 | 7.30 | Sorbact Ribbon Gauze S98120 [BV] |

## ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

### dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

4911L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *82.79 | 7.30 | Nu-Gel 2497 [KI] |

## ▪ DRESSING HYDROGEL SHEET

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### dressing hydrogel sheet 10 cm x 10 cm dressing, 5

4806Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *55.35 | 7.30 | Hydrosorb 900854 [HR] |

## ▪ DRESSING HYDROPHOBIC

### dressing hydrophobic 15 cm x 15 cm dressing, 10

11394Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 312.81 | 7.30 | Sorbact Foam Gentle Border 98533 [BV] |

### dressing hydrophobic 20 cm x 20 cm dressing, 10

11403E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 245.07 | 7.30 | Sorbact Superabsorbent 98503 [BV] |

### dressing hydrophobic 15 cm x 15 cm foam dressing, 10

11404F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 205.56 | 7.30 | Sorbact Foam Dressing S98315 [BV] |

### dressing hydrophobic 10 cm x 10 cm dressing, 10

11392N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 199.91 | 7.30 | Sorbact Foam Gentle Border 98532 [BV] |

### dressing hydrophobic 10 cm x 10 cm dressing, 10

11402D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 90.94 | 7.30 | Sorbact Superabsorbent 98501 [BV] |

## ▪ DRESSING LIPIDOCOLLOID MODERATE EXUDATE

### dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 16

13026N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 121.00 | 7.30 | UrgoTul Lite Border 100357 [UG] |

### dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 10

13331P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | .. | 80.25 | 7.30 | UrgoTul Lite Border 10035710 [UG] |

## ▪ DRESSING NON ADHERENT

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1

4243H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 64.99 | 7.30 | Mepitel 290510 [MH] |

### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1

4244J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 104.99 | 7.30 | Mepitel 290710 [MH] |

## ▪ DRESSING NON ADHERENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing non adherent 7.5 cm x 10 cm dressing, 10**

4944F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 20.66 | 7.30 | Atrauman 499513 [HR] |

## ▪ DRESSING NON ADHERENT

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing non adherent 10 cm x 10 cm dressing, 10**

4861W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 44.00 | 7.30 | Melolin 66974933 [SN] |

**dressing non adherent 10 cm x 10 cm dressing, 5**

4862X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *31.93 | 7.30 | Cutilin Non-Stick Wound Pad 36361375 [SN] |

**dressing non adherent 5 cm x 5 cm dressing, 5**

4819P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *22.33 | 7.30 | Cutilin Non-Stick Wound Pad 36361374 [SN] |

**dressing non adherent 5 cm x 5 cm dressing, 5**

4860T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | .. | .. | *23.95 | 7.30 | Melolin 36361357 [SN] |

## ▪ DRESSING NON-ADHERENT ABSORBENT

**dressing non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10**

12834L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 52.77 | 7.30 | Mextra Superabsorbent 610300 [MH] |

**dressing non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10**

12833K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 90.40 | 7.30 | Mextra Superabsorbent 610500 [MH] |

**dressing non-adherent absorbent 10 cm x 13 cm dressing, 50**

12832J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 57.61 | 7.30 | Mesorb 677001 [MH] |

**dressing non-adherent absorbent 10 cm x 23 cm dressing, 50**

12825B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 78.04 | 7.30 | Mesorb 677401 [MH] |

**dressing non-adherent absorbent 23 cm x 25 cm dressing, 30**

12824Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 101.05 | 7.30 | Mesorb 677701 [MH] |

**dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10**

11717Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 27.18 | 7.30 | Vliwasorb Pro 32641 [LC] |

**dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10**

12837P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 33.74 | 7.30 | Mextra Superabsorbent 610000 [MH] |

**dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10**

11715N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 38.04 | 7.30 | Vliwasorb Pro 32643 [LC] |

**dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10**

11718R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 50.62 | 7.30 | Vliwasorb Pro 32644 [LC] |

## ▪ DRESSING NON-ADHERENT ABSORBENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### dressing non-adherent absorbent 10 cm x 10 cm hydroactive dressing, 10

12600E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 38.85 | 7.30 | Zetuvit Plus 413710 [HR] |

### dressing non-adherent absorbent 10 cm x 20 cm hydroactive dressing, 10

12593T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 45.31 | 7.30 | Zetuvit Plus 413711 [HR] |

### dressing non-adherent absorbent 20 cm x 40 cm hydroactive dressing, 10

12599D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 97.03 | 7.30 | Zetuvit Plus 413715 [HR] |

## ▪ DRESSING NON-ADHERENT WITH SILICONE

### dressing non-adherent with silicone 10 cm x 18 cm dressing, 10

12196X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 309.64 | 7.30 | Mepitel One 289500 [MH] |

### dressing non-adherent with silicone 5 cm x 7.5 cm dressing, 10

12208M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 92.66 | 7.30 | Mepitel One 289100 [MH] |

## ▪ DRESSING NON-ADHERENT WITH SILICONE

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### dressing non-adherent with silicone 7.5 cm x 10 cm dressing, 5

12651W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 65.76 | 7.30 | Atrauman Silicone 499561 [HR] |

## ▪ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE

### dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10

13013X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 204.66 | 7.30 | UrgoStart Plus Border 100460 [UG] |

### dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13014Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 266.15 | 7.30 | UrgoStart Plus Non Adhesive 100441 [UG] |

### dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13019F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 279.66 | 7.30 | UrgoStart Plus Border 100461 [UG] |

### dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10

13024L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 637.02 | 7.30 | UrgoStart Plus Border 100462 [UG] |

### dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 5

13018E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 306.80 | 7.30 | UrgoStart Plus Non Adhesive 100442 [UG] |

## ▪ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10**

13025M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 209.64 | 7.30 | UrgoStart Plus Pad 100421 [UG] |

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10**

13012W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | .. | 474.85 | 7.30 | UrgoStart Plus Pad 100422 [UG] |

## ▪ DRESSING TULLE NON-ADHERENT PRIMARY WOUND CONTACT LAYER PARAFFIN

**dressing tulle non-adherent primary wound contact layer paraffin 7.6 cm x 7.6 cm dressing, 1**

4909J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 10 | 1 | .. | *21.07 | 7.30 | Adaptic 2012 [KI] |

## ▪ DRESSING WITH SILVER

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 10 cm x 10 cm tulle dressing, 10**

12591Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 116.59 | 7.30 | Atrauman Ag 499573 [HR] |

**dressing with silver 10 cm x 10 cm tulle dressing, 3**

4648P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 45.85 | 7.30 | Atrauman Ag 499572 [HR] |

## ▪ DRESSING WITH SILVER

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5**

4647N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 184.45 | 7.30 | Biatain Ag 9632 [CT] |

**dressing with silver 10 cm x 10 cm hydroactive dressing, 5**

4646M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 169.74 | 7.30 | Biatain Ag 9622 [CT] |

## ▪ GAUZE AND COTTON TISSUE COMBINE ROLL

**gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1**

4761N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 22.37 | 7.30 | JJ 12010 [JJ] |

**gauze and cotton tissue combine roll 9 cm x 10 m wrapped pack roll, 1**

4767X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 17.76 | 7.30 | BSN 2902165 [BV] |

## ▪ PAD WOUND DEBRIDEMENT

**Note** If the wound has not healed during this period, further use is to be discontinued after initial pack, no repeats. Where wounds remain unresponsive to standard treatment, patient should be referred on to a specialist.

**pad wound debridement 10 cm x 10 cm pad, 5**

| 11383D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 93.36 | 7.30 | Debrisoft [LC] |

**pad wound debridement pad, 5**

| 11391M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 93.36 | 7.30 | Debrisoft Lolly [LC] |

## ▪ POVIDONE-IODINE

**povidone-iodine 9.5 cm x 9.5 cm dressing, 25**

| 10847X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | .. | 79.54 | 7.30 | Inadine [KI] |

## ▪ SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

**sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL**

| 11134B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 3 | .. | 32.34 | 7.30 | Microdacyn [TF] |

## ▪ TAPE NON WOVEN RETENTION POLYACRYLATE

**tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll**

| 4915Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 18.62 | 7.30 | Medipore 2961 [MM] |

## ▪ TAPE NON WOVEN RETENTION POLYACRYLATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll**

| 4917T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.14 | 7.30 | Mefix 310250 [MH] |

## ▪ TAPE PLASTER ADHESIVE ELASTIC

**tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll**

| 4780N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 19.52 | 7.30 | Leukoplast 01071-00 [BV] |

**tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll**

| 4781P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 25.46 | 7.30 | Leukoplast 01072-00 [BV] |

**tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll**

| 4782Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 29.14 | 7.30 | Leukoplast 01073-00 [BV] |

## ▪ TAPE PLASTER ADHESIVE HYPOALLERGENIC

**tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll**

| 4848E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.15 | 7.30 | Nexcare Durable Cloth First Aid Tape 799 [MM] |

**tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll**

| 4849F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.15 | 7.30 | Nexcare Gentle Paper First Aid Tape 789 [MM] |

**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

| 4783R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | .. | .. | 17.06 | 7.30 | Leukopor 2471 [BV] |

**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

4785W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 17.33 | 7.30 | Leukosilk 1021 [BV] |

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4787Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 19.87 | 7.30 | Leukosilk 1022 [BV] |

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4794H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 19.34 | 7.30 | Leukopor 2472 [BV] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4788B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 22.37 | 7.30 | Leukoflex 1124 [BV] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4789C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 23.69 | 7.30 | Leukosilk 1024 [BV] |

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4790D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 22.86 | 7.30 | Leukopor 2474 [BV] |

## ▪ TAPE PLASTER ADHESIVE WITH SILICONE

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**tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll**

4239D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 25.99 | 7.30 | Mepitac 298300 [MH] |

**tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll**

4240E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | .. | .. | 25.99 | 7.30 | Mepitac 298400 [MH] |

# Extemporaneously Prepared Benefits

# Drug Tariff

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Acacia, powdered | BP | 0.03 | 0.34 | 3.09 | 19.62 |
| Acetic Acid (33 per cent) | BP | 0.02 | 0.18 | 1.75 | 17.53 |
| Acetic Acid (6 per cent) | BP | 0.01 | 0.04 | 0.40 | 4.02 |
| Acetone (use as additive only) | BP | 0.02 | 0.20 | 1.78 | 15.85 |
| Alum | BP | 0.07 | 0.70 | 6.27 | 55.73 |
| Aluminium Acetate Solution | BP | 0.02 | 0.22 | 2.01 | 17.86 |
| Anise Water Concentrated 1 in 40 | BP | 0.01 | 0.08 | 0.80 | 8.02 |
| Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.06 | 0.51 | 4.57 |
| Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures) | BP | 0.22 | 2.22 | 19.99 | 126.90 |
| Aspirin | BP | 0.38 | 3.76 | 33.87 | 301.08 |
| Belladonna Tincture | BP | 0.04 | 0.36 | 3.26 | 28.99 |
| Benzocaine | BP | 0.27 | 2.73 | 15.62 | 156.20 |
| Benzoic Acid | BP | 0.21 | 2.13 | 19.13 | 121.48 |
| Benzoic Acid Compound Ointment | APF | 0.02 | 0.22 | 2.01 | 17.91 |
| Benzoic Acid Solution | BP | 0.02 | 0.23 | 2.29 | 22.87 |
| Benzoin Compound Tincture | BP | 0.05 | 0.49 | 4.43 | 39.39 |
| Boric Acid (use as additive only) | BP | 0.06 | 0.64 | 5.76 | 36.56 |
| Boric Acid, Olive Oil and Zinc Oxide Ointment | QHF | 0.02 | 0.22 | 1.99 | 12.67 |
| Calcium Hydroxide | BP | 0.26 | 2.64 | 23.75 | 150.82 |
| Calcium Hydroxide Solution | BP | 0.01 | 0.04 | 0.36 | 3.65 |
| Castor Oil (use as additive only) | BP | 0.01 | 0.13 | 1.16 | 10.33 |
| Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.07 | 0.61 | 5.44 |
| Cetrimide Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.13 | 1.17 | 10.42 |
| Chlorhexidine Acetate (use as additive only) | BP | 0.63 | 6.29 | 35.96 | 359.60 |
| Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.05 | 0.49 | 4.32 |
| Chloroform (use as additive only) | BP | 0.11 | 1.06 | 9.51 | 84.57 |
| Chloroform Spirit | BP | 0.01 | 0.10 | 0.96 | 9.59 |
| Chloroform Water Concentrated 1 in 40 | APF 15 | 0.01 | 0.13 | 1.25 | 12.54 |
| Citric Acid Monohydrate | BP | 0.11 | 1.06 | 9.55 | 60.62 |
| Coal Tar | BP | 0.06 | 0.55 | 4.98 | 44.27 |
| Coal Tar Solution | BP | 0.03 | 0.27 | 2.43 | 15.45 |
| Cocaine Hydrochloride | BP | 29.29 | 292.85 | 1673.43 | 16734.34 |
| Coconut Oil | BP | 0.06 | 0.55 | 4.96 | 31.50 |
| Codeine Linctus | APF | 0.02 | 0.17 | 1.53 | 9.70 |
| Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children) | BP | 1.35 | 13.53 | 77.30 | 773.00 |
| Collodion Flexible | BP | 0.51 | 5.11 | 45.97 | 291.87 |
| Dithranol | BP | 4.17 | 41.67 | 238.14 | 2381.36 |
| Emulsifying Ointment (for use only as a base combined with active ingredients) | BP | 0.02 | 0.16 | 1.45 | 12.88 |
| Ephedrine Hydrochloride (may only be prescribed in nasal instillations) | BP | 2.88 | 28.79 | 259.07 | 1644.88 |
| Ethanol (90 per cent) (use as additive only) | BP | 0.01 | 0.06 | 0.51 | 4.53 |
| Ethanol (96 per cent) (use as additive only) | BP | 0.01 | 0.07 | 0.61 | 5.45 |
| Ether Solvent (use as additive only) | BP | 0.29 | 2.35 | 18.83 | 167.36 |
| Eucalyptus Oil (use as additive only) | BP | 0.02 | 0.20 | 1.79 | 15.91 |
| Ferrous Sulfate | BP | 0.08 | 0.83 | 7.48 | 47.48 |
| Formaldehyde Solution | BP | 0.03 | 0.33 | 3.00 | 26.68 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Gentian Alkaline Mixture | APF | 0.01 | 0.09 | 0.68 | 6.00 |
| Glycerol | BP | 0.01 | 0.12 | 1.04 | 9.21 |
| Honey Purified (use as additive only) | BP 1993 | 0.01 | 0.03 | 0.27 | 2.44 |
| Hydroxybenzoate Compound Solution | APF | 0.09 | 0.68 | 5.42 | 48.17 |
| Iodine | BP | 1.03 | 10.32 | 58.95 | 589.53 |
| Iodine Alcoholic Solution | BP | 0.04 | 0.40 | 3.63 | 23.07 |
| Iodine Aqueous Oral Solution | BP | 0.04 | 0.41 | 3.71 | 23.55 |
| Kaolin Mixture | BPC 1968 | 0.04 | 0.38 | 3.45 | 30.68 |
| Kaolin and Opium Mixture | APF 14 | 0.01 | 0.10 | 0.82 | 7.27 |
| Lactic Acid | BP | 0.34 | 3.36 | 30.21 | 191.81 |
| Lavender Spike Oil | BPC 1968 | 0.13 | 1.29 | 11.57 | 73.44 |
| Liquorice Liquid Extract | BP | 0.19 | 1.85 | 16.69 | 148.34 |
| Magnesium Carbonate Light | BP | 0.05 | 0.37 | 2.92 | 25.99 |
| Magnesium Sulfate (may only be prescribed for other than oral use) | BP | 0.01 | 0.03 | 0.28 | 2.48 |
| Magnesium Trisilicate | BP | 0.06 | 0.59 | 5.27 | 46.82 |
| Menthol, Racemic or Levomenthol | BP | 0.28 | 2.81 | 25.28 | 160.48 |
| Methyl Hydroxybenzoate | BP | 0.47 | 4.73 | 42.60 | 270.48 |
| Methyl Hydroxybenzoate Solution | APF | 0.05 | 0.48 | 4.76 | 47.62 |
| Methylated Industrial Spirit (use as additive only) | BP | 0.01 | 0.01 | 0.12 | 1.07 |
| Olive Oil (use as additive only) | BP | 0.01 | 0.10 | 0.89 | 7.92 |
| Paraffin Hard | BP | 0.07 | 0.71 | 6.40 | 56.85 |
| Paraffin Light Liquid | BP | 0.01 | 0.14 | 1.25 | 7.96 |
| Paraffin Liquid (use as additive only) | BP | 0.01 | 0.10 | 0.88 | 7.82 |
| Paraffin Soft White | BP | 0.01 | 0.08 | 0.68 | 6.03 |
| Peppermint Oil (use as additive only) | BP | 0.10 | 1.00 | 9.03 | 57.32 |
| Peppermint Water Concentrated 1 in 40 (use as additive only) | APF 16 | 0.05 | 0.46 | 4.10 | 36.48 |
| Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy) | BP | 1.39 | 13.94 | 125.45 | 796.48 |
| Phenol Liquefied (not available for ear drops) | BP | 0.05 | 0.55 | 4.93 | 31.32 |
| Podophyllum Resin | BP | 4.63 | 46.31 | 264.64 | 2646.40 |
| Potassium Citrate | BP | 0.03 | 0.33 | 2.96 | 26.29 |
| Potassium Iodide | BP | 0.55 | 5.51 | 49.55 | 314.62 |
| Potassium Permanganate | BP | 0.04 | 0.43 | 3.83 | 34.07 |
| Propyl Hydroxybenzoate | BP | 0.44 | 4.38 | 39.45 | 250.48 |
| Propylene Glycol | BP | 0.03 | 0.28 | 2.52 | 16.01 |
| Resorcinol | BP | 0.45 | 3.57 | 28.59 | 254.15 |
| Salicylic Acid | BP | 0.05 | 0.47 | 4.26 | 27.08 |
| Salicylic Acid Ointment | APF | 0.02 | 0.16 | 1.45 | 12.91 |
| Salicylic Acid Ointment | BP | 0.02 | 0.16 | 1.45 | 12.91 |
| Simple Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.16 | 1.48 | 13.19 |
| Simple Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.14 | 1.11 | 9.88 |
| Sodium Bicarbonate | BP | 0.04 | 0.36 | 3.22 | 28.58 |
| Sodium Chloride | BP | 0.03 | 0.29 | 2.58 | 22.89 |
| Sodium Chloride Solution | BP | 0.01 | 0.01 | 0.13 | 1.27 |
| Sodium Citrate | BP | 0.15 | 1.55 | 13.91 | 88.29 |
| Sodium Thiosulfate (use as additive only) | BP | 0.09 | 0.88 | 7.89 | 70.16 |
| Starch | BP | 0.02 | 0.22 | 1.94 | 17.23 |
| Sulfur Ointment (for use only as a base combined with active ingredients) | BP 1980 | 0.01 | 0.15 | 1.45 | 14.52 |
| Sulfur Precipitated | BP 1980 | 0.03 | 0.29 | 2.65 | 16.83 |
| Syrup | BP | 0.01 | 0.06 | 0.57 | 5.09 |
| Talc Purified, sterilised | BP | 5.54 | 55.37 | 498.35 | 4429.78 |
| Thymol | BP | 0.56 | 5.64 | 50.79 | 322.48 |
| Thymol Compound Mouth Wash | APF 15 | 0.01 | 0.10 | 0.94 | 8.37 |
| Tragacanth Compound Powder | BP 1980 | 0.07 | 0.57 | 4.58 | 40.73 |
| Tragacanth Mucilage | APF 13 | 0.01 | 0.11 | 1.07 | 10.72 |
| Tragacanth Mucilage | BPC 1973 | 0.01 | 0.10 | 1.00 | 10.01 |
| Tragacanth, powdered | BP | 0.70 | 7.03 | 63.28 | 401.77 |
| Trichloroacetic Acid | BP 1980 | 0.32 | 3.25 | 29.23 | 185.56 |
| Triethanolamine | BP | 0.17 | 1.69 | 15.17 | 96.29 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions) | BP | 0.00 | 0.00 | 0.00 | 9.11 |
| Water Purified | BP | 0.01 | 0.01 | 0.11 | 1.02 |
| Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.03 | 0.21 | 1.64 | 14.55 |
| Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.19 | 1.48 | 13.18 |
| Wool Fat | BP | 0.03 | 0.33 | 2.93 | 26.05 |
| Wool Fat Hydrous | BP | 0.03 | 0.30 | 2.66 | 23.67 |
| Zinc Compound Paste | BP | 0.04 | 0.45 | 4.03 | 35.81 |
| Zinc Cream (for use only as a base combined with active ingredients) | BP | 0.03 | 0.32 | 2.88 | 25.60 |
| Zinc Oxide | BP | 0.03 | 0.34 | 3.05 | 27.10 |
| Zinc Sulfate | BP | 0.08 | 0.83 | 7.49 | 47.55 |
| Zinc and Salicylic Acid Paste | BP | 0.04 | 0.37 | 3.36 | 29.86 |

# Container Prices

| Type | Container | Price $ |
|---|---|---|
| Dispensing Bottles | 25mL | 1.74 |
| Dispensing Bottles | 50mL | 0.73 |
| Dispensing Bottles | 100mL | 0.85 |
| Dispensing Bottles | 200mL | 0.87 |
| Dispensing Bottles | 500mL | 1.28 |
| Poison Bottles | 25mL | 0.92 |
| Poison Bottles | 50mL | 1.23 |
| Poison Bottles | 100mL | 1.28 |
| Poison Bottles | 200mL | 1.35 |
| Poison Bottles | 500mL | 2.00 |
| Poison Bottles | 600mL | 4.05 |
| Poison Bottles | 1000mL | 3.99 |
| Dropper Containers (Glass) | 15mL | 1.68 |
| Dropper Containers (Polythene) | 15mL | 0.98 |
| Screw Cap Jars | 25g | 1.07 |
| Screw Cap Jars | 50g | 1.36 |
| Screw Cap Jars | 100g | 1.37 |
| Screw Cap Jars | 200g | 0.77 |
| Screw Cap Jars | 500g | 2.19 |
| Screw Cap Jars | 1000g | 4.39 |

# Standard Formula Preparations

| Code | Item | Reference | DPMQ $ | MRVSN $ |
|---|---|---|---|---|
| | **Creams** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7502W | Salicylic Acid and Sulfur Aqueous | APF | 17.71 | 19.51 |
| | **Ear Drops** | | | |
| | **(Maximum Quantity 15 ml and 2 Repeats)** | | | |
| 7643G | Aluminium Acetate | BP | 14.40 | 16.20 |
| 7642F | Aluminium Acetate | APF | 13.27 | 15.07 |
| 7314Y | Sodium Bicarbonate | APF & BP | 12.29 | 14.09 |
| 7313X | Spirit | APF | 11.86 | 13.66 |
| | **Inhalations** | | | |
| | **(Maximum Quantity 50 ml and 1 Repeat)** | | | |
| 7484X | Benzoin and Menthol | APF | 36.16 | 30.00 |
| 7308P | Menthol | APF | 16.94 | 18.74 |
| 7310R | Menthol and Eucalyptus | BP1980 | 17.59 | 19.39 |
| | **Linctuses containing Codeine Phosphate** | | | |
| | **(Maximum Quantity 100 ml and 0 Repeat)** | | | |
| 7530H | Codeine | APF | 20.96 | 22.76 |
| | **Lotions** | | | |
| | **(Maximum Quantity 200 ml and 2 Repeats)** | | | |
| 7709R | Aluminium Acetate Aqueous | APF | 15.71 | 17.51 |
| | **Mixtures, Other** | | | |
| | **(Maximum Quantity 200 ml and 4 Repeats)** | | | |
| 7348R | Kaolin | BPC 1968 | 55.10 | 30.00 |
| 7342K | Magnesium Trisilicate | BPC 1968 | 28.07 | 29.87 |
| 7343L | Magnesium Trisilicate and Belladonna | BPC 1968 | 29.72 | 30.00 |
| | **Ointments, Waxes** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7914M | Benzoic Acid Compound | APF & BP | 29.68 | 30.00 |
| 7902X | Boric Acid, Olive Oil and Zinc Oxide | QHF | 24.44 | 26.24 |
| 7926E | Salicylic Acid | APF | 24.69 | 26.49 |
| 7928G | Salicylic Acid (extemporaneous formula) | BP | 24.69 | 26.49 |
| | **Paints** | | | |
| | **(Maximum Quantity 25 ml and 1 Repeat)** | | | |
| 7567G | Podophyllin Compound | APF 16 & BP | 194.42 | 30.00 |
| 7568H | Salicylic Acid | APF | 115.94 | 30.00 |
| | **Pastes, Other** | | | |
| | **(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7558T | Zinc | APF & BP | 47.59 | 30.00 |
| | **Powders for Internal Use** | | | |
| | **(Maximum Quantity 100 g and 2 Repeats)** | | | |
| 7545D | Magnesium Trisilicate | BP | 58.00 | 30.00 |

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

| Code | Preparation | Maximum Quantity | Number of Repeats |
|---|---|---|---|
| 13Q | Creams | 100 g | 1 |
| 48M | Dusting Powders | 100 g | 1 |
| 15T | Ear Drops | 15 ml | 2 |
| 19B | Eye Drops containing Cocaine Hydrochloride | 15 ml | .. |
| 22E | Eye Drops, Other | 15 ml | 5 |
| 23F | Eye Lotions | 200 ml | 2 |
| 29M | Inhalations | 50 ml | 1 |
| 64J | Linctuses containing Codeine Phosphate | 100 ml | .. |
| 34T | Linctuses, Other | 100 ml | 2 |
| 39C | Lotions | 200 ml | 2 |
| 65K | Mixtures containing Codeine Phosphate | 200 ml | .. |
| 66L | Mixtures for Children containing Codeine Phosphate | 100 ml | .. |
| 41E | Mixtures for Children, Other | 100 ml | 4 |
| 40D | Mixtures, Other | 200 ml | 4 |
| 30N | Mouth Washes | 200 ml | 1 |
| 42F | Nasal Instillations | 15 ml | 2 |
| 43G | Ointments, Waxes | 100 g | 1 |
| 44H | Paints | 25 ml | 1 |
| 63H | Pastes containing Cocaine Hydrochloride | 25 g | .. |
| 45J | Pastes, Other | 100 g | 1 |
| 49N | Powders for Internal Use | 100 g | 2 |
| 52R | Solutions | 200 ml | 2 |

# Index of Manufacturers' Code

| Code | Manufacturer |
|---|---|
| **AB** | Abbott Australasia Pty Ltd |
| **AE** | AFT Pharmaceuticals (AU) Pty Ltd |
| **AF** | Alphapharm Pty Ltd |
| **AL** | Alphapharm Pty Ltd |
| **AN** | Amgen Australia Pty Limited |
| **AP** | AstraZeneca Pty Ltd |
| **AQ** | Alcon Laboratories (Australia) Pty Ltd |
| **AS** | Aspen Pharmacare Australia Pty Limited |
| **AV** | sanofi-aventis Australia Pty Ltd |
| **BB** | Blackmores Limited |
| **BD** | Biogen Australia Pty Ltd |
| **BE** | Beiersdorf Australia Ltd |
| **BG** | Sandoz Pty Ltd |
| **BN** | Bayer Australia Ltd |
| **BQ** | Bristol-Myers Squibb Australia Pty Ltd |
| **BR** | B. Braun Australia Pty Ltd |
| **BV** | BSN medical (Aust.) Pty Ltd |
| **BX** | Baxter Healthcare Pty Limited |
| **BY** | Boehringer Ingelheim Pty Ltd |
| **BZ** | Boucher & Muir Pty Ltd |
| **CC** | ConvaTec Australia Pty Ltd |
| **CF** | CNS Pharma Pty Ltd |
| **CH** | Apotex Pty Ltd |
| **CJ** | Celgene Pty Limited |
| **CR** | Pharmacor Pty Limited |
| **CS** | Seqirus (Australia) Pty Ltd |
| **CT** | Coloplast Pty Ltd |
| **CU** | Care Pharmaceuticals Pty Limited |
| **CX** | Contact Lens Centre Australia Limited |
| **DE** | Stallergenes Australia Pty Ltd |
| **DJ** | De Fries Industries Pty Ltd |
| **DQ** | Church & Dwight (Australia) Pty Ltd |
| **DV** | Medical Developments International Limited |
| **DX** | Ascensia Diabetes Care Australia Pty Limited |
| **DZ** | Medsurge Healthcare Pty Ltd |
| **EA** | Amneal Pharmaceuticals Pty Ltd |
| **ED** | Amneal Pharmaceuticals Pty Ltd |
| **EF** | Amneal Pharmaceuticals Pty Ltd |
| **EI** | Eisai Australia Pty Ltd |
| **EJ** | Encapsulate Pharma Pty Ltd |
| **EO** | Ego Pharmaceuticals Pty Ltd |
| **EU** | Chiesi Australia Pty Ltd |
| **EV** | Teva Pharma Australia Pty Ltd |
| **EW** | Celltrion Healthcare Australia Pty Ltd |
| **FB** | Pierre Fabre Australia Pty Ltd |
| **FD** | Dr Falk Pharma Australia Pty Ltd |
| **FF** | Phebra Pty Ltd |
| **FG** | Phebra Pty Ltd |
| **FI** | Boehringer Ingelheim Pty Ltd |
| **FJ** | Pharmaco (Australia) Limited |
| **FK** | A.Menarini Australia Pty Limited |
| **FP** | Ferring Pharmaceuticals Pty Limited |
| **FQ** | Pharmaco (Australia) Limited |
| **FX** | Gedeon Richter Australia Pty Ltd |
| **FZ** | Pfizer Australia Pty Ltd |
| **GA** | Galderma Australia Pty Ltd |
| **GC** | GlaxoSmithKline Australia Pty Ltd |
| **GG** | Gem Pharma Pty Ltd |
| **GH** | Amdipharm Mercury (Australia) Pty Limited |
| **GI** | Gilead Sciences Pty Limited |
| **GJ** | HALEON AUSTRALIA PTY LTD |
| **GK** | GlaxoSmithKline Australia Pty Ltd |
| **GN** | Actavis Pty Ltd |
| **GO** | Viatris Pty Ltd |
| **GQ** | Generic Health Pty Ltd |
| **GT** | Viatris Pty Ltd |
| **GX** | Apotex Pty Ltd |
| **GZ** | sanofi-aventis Australia Pty Ltd |
| **HB** | Besins Healthcare Australia Pty Ltd |
| **HD** | Department of Health |
| **HQ** | Generic Health Pty Ltd |
| **HR** | Paul Hartmann Pty Ltd |
| **HT** | BTC Speciality Health Pty Ltd |
| **HW** | HAMELN PHARMA PTY. LTD. |
| **HX** | Sandoz Pty Ltd |
| **IB** | Apotex Pty Ltd |
| **IE** | BeiGene AUS Pty Ltd |
| **IG** | Sigma Company Limited |
| **IJ** | I-Care Pharma Distributors Pty Ltd |
| **IL** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IM** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IO** | BioMarin Pharmaceutical Australia Pty Ltd |
| **IQ** | Alcon Laboratories (Australia) Pty Ltd |
| **IR** | Indivior Pty Ltd |
| **IS** | Ipsen Pty Ltd |
| **IT** | InterPharma Pty Ltd |
| **IX** | Clinect Pty Ltd |
| **IY** | Clinect Pty Ltd |
| **JB** | Apotex Pty Ltd |
| **JC** | Janssen-Cilag Pty Ltd |
| **JJ** | Johnson & Johnson Medical Pty Ltd |
| **JO** | Juno Pharmaceuticals Pty Ltd |
| **JT** | Johnson & Johnson Pacific Pty Limited |
| **JU** | Juno Pharmaceuticals Pty Ltd |
| **JX** | Juno Pharmaceuticals Pty Ltd |
| **JZ** | Juniper Biologics Pty Ltd |
| **KE** | Kendall Australasia Pty Ltd |
| **KI** | KCI Medical Australia Pty Ltd |
| **KO** | KYOWA KIRIN AUSTRALIA PTY LTD |
| **KP** | Eli Lilly Australia Pty Ltd |
| **KY** | Key Pharmaceuticals Pty Ltd |
| **LC** | Lohmann & Rauscher Pty Ltd |
| **LI** | Luminarie Pty Ltd |
| **LL** | Astellas Pharma Australia Pty Ltd |
| **LM** | Link Medical Products Pty Ltd |
| **LN** | Aspen Pharmacare Australia Pty Limited |
| **LO** | Leo Pharma Pty Ltd |
| **LQ** | Astellas Pharma Australia Pty Ltd |
| **LR** | Cipla Australia Pty Ltd |
| **LS** | Astellas Pharma Australia Pty Ltd |
| **LT** | Aspen Pharmacare Australia Pty Limited |
| **LU** | Lundbeck Australia Pty Ltd |
| **LV** | Luminarie Pty Ltd |
| **LX** | Lawley Pharmaceuticals Pty Ltd |
| **LY** | Eli Lilly Australia Pty Ltd |
| **MF** | Mundipharma Pty Limited |
| **MH** | Molnlycke Health Care Pty Ltd |
| **MK** | Merck Sharp & Dohme (Australia) Pty Ltd |
| **MM** | 3M Pharmaceuticals Australia Pty Ltd |
| **MQ** | Alphapharm Pty Ltd |
| **MT** | Mentholatum Australasia Pty Ltd |
| **MW** | Biomed Aust Pty Limited |
| **NE** | Norgine Pty. Ltd. |
| **NF** | Novo Nordisk Pharmaceuticals Pty. Limited |
| **NI** | Novo Nordisk Pharmaceuticals Pty. Limited |
| **NM** | Novartis Pharmaceuticals Australia Pty Limited |
| **NO** | Novo Nordisk Pharmaceuticals Pty. Limited |
| **NQ** | Takeda Pharmaceuticals Australia Pty. Ltd. |
| **NT** | Nestle Australia Ltd |
| **NU** | Nutricia Australia Pty Limited |
| **NV** | Novartis Pharmaceuticals Australia Pty Limited |
| **OB** | Oral B Laboratories Pty Ltd |
| **OC** | Accord Healthcare Pty. Ltd. |
| **OE** | Omegapharm Pty Ltd |
| **OH** | Orpharma Pty Ltd |
| **OJ** | The Trustee for ORSPEC PHARMA UNIT TRUST |
| **OM** | Colgate Oral Care |
| **ON** | Orion Laboratories Pty. Ltd. |

| Code | Manufacturer |
|---|---|
| **OQ** | Organon Pharma Pty Ltd |
| **OS** | Otsuka Australia Pharmaceutical Pty. Ltd |
| **OU** | Oraderm Pharmaceuticals Pty Ltd |
| **OV** | Organon Pharma Pty Ltd |
| **OW** | Arrow Pharma Pty Ltd |
| **OX** | Orion Pharma (Aus) Pty Limited |
| **PB** | Pharmaco (Australia) Limited |
| **PF** | Pfizer Australia Pty Ltd |
| **PK** | Fresenius Kabi Australia Pty Limited |
| **PP** | Petrus Pharmaceuticals Pty Ltd |
| **PY** | Procter & Gamble Pharmaceuticals Australia Pty Ltd |
| **QH** | Cortex Health Pty Ltd |
| **QS** | Sandoz Pty Ltd |
| **QY** | Pro Pharmaceuticals Group Pty. Ltd. |
| **QZ** | Pro Pharmaceuticals Group Pty. Ltd. |
| **RA** | Sun Pharma ANZ Pty Ltd |
| **RB** | Bio Revive Pty Ltd |
| **RC** | Reckitt Benckiser (Australia) Pty Limited |
| **RF** | Arrow Pharma Pty Ltd |
| **RI** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **RJ** | Recordati Rare Diseases Australia Pty. Ltd. |
| **RM** | Pharmacor Pty Limited |
| **RN** | Sun Pharma ANZ Pty Ltd |
| **RO** | Roche Products Pty Ltd |
| **RQ** | Reach Pharmaceuticals Pty Ltd |
| **RW** | Arrow Pharma Pty Ltd |
| **RX** | Servier Laboratories (Aust.) Pty. Ltd. |
| **RZ** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **SA** | SciGen (Australia) Pty Limited |
| **SB** | Nutricia Australia Pty Limited |
| **SE** | Servier Laboratories (Aust.) Pty. Ltd. |
| **SG** | Merck Healthcare Pty Ltd |
| **SI** | Sigma Company Limited |
| **SN** | Smith & Nephew Pty Limited |
| **SS** | SSL Australia Pty Ltd |
| **SW** | sanofi-aventis Australia Pty Ltd |
| **SY** | Bayer Australia Ltd |
| **SZ** | Sandoz Pty Ltd |
| **TB** | Teva Pharma Australia Pty Ltd |
| **TD** | STADA Pharmaceuticals Australia Pty Limited |
| **TF** | Te Arai BioFarma Limited |
| **TG** | ANTENGENE (AUS) PTY. LTD. |
| **TK** | Takeda Pharmaceuticals Australia Pty. Ltd. |
| **TM** | Technipro PulmoMed Pty Ltd |
| **TN** | Medtas Pty Ltd |
| **TQ** | Terumo BCT Australia Pty Limited |
| **TS** | Specialised Therapeutics Australia Pty Ltd |
| **TT** | Theramex Australia Pty Ltd |
| **TW** | Apotex Pty Ltd |
| **TX** | Apotex Pty Ltd |
| **TY** | Apotex Pty Ltd |
| **UC** | UCB Australia Proprietary Limited |
| **UG** | Urgo Medical Australia Pty Ltd |
| **UJ** | Upjohn Australia Pty Ltd |
| **UL** | Bausch & Lomb (Australia) Pty Ltd |
| **UM** | Unomedical Pty Ltd |
| **UN** | Unilever Australia Limited |
| **UO** | Bausch & Lomb (Australia) Pty Ltd |
| **UR** | Camurus Pty Ltd |
| **VB** | AbbVie Pty Ltd |
| **VE** | AbbVie Pty Ltd |
| **VF** | Vitaflo Australia Pty Limited |
| **VI** | ViiV Healthcare Pty Ltd |
| **VL** | Vifor Pharma Pty Limited |
| **VO** | Avallon Pharmaceuticals Pty Limited |
| **VR** | Vertex Pharmaceuticals (Australia) Pty. Ltd. |
| **VZ** | Sanofi-aventis Healthcare Pty Ltd |
| **WA** | sanofi-aventis Australia Pty Ltd |
| **XC** | Southern Cross Pharma Pty Ltd |

| Code | Manufacturer |
|---|---|
| **XH** | MS Health Pty Ltd |
| **XI** | Alexion Pharmaceuticals Australasia Pty Ltd |
| **XN** | Southern XP Pty Ltd |
| **XO** | Echo Therapeutics Pty Ltd |
| **XT** | Arrotex Pharmaceuticals Pty Ltd |
| **XW** | Arrotex Pharmaceuticals Pty Ltd |
| **XY** | MAXX PHARMA PTY LTD |
| **YC** | Cipla Australia Pty Ltd |
| **YN** | Mayne Pharma International Pty Ltd |
| **YT** | Mayne Products Pty Ltd |
| **ZA** | AstraZeneca Pty Ltd |
| **ZE** | Seekwell Pty Ltd |
| **ZO** | Swedish Orphan Biovitrum Pty Ltd |
| **ZP** | Medis Pharma Pty Ltd |
| **ZS** | Strides Pharma Science Pty Ltd |

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